**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 unless they fall into category 2 below.

Patients considered for FreeStyle Libre® flash glucose monitoring should have:

1. Type 1 diabetes and clinically indicated as requiring intensive blood glucose monitoring i.e. finger prick testing at least 8 times per day, as demonstrated on a meter download/review over the past 3 months.
2. Any form of diabetes on haemodialysis and on insulin treatment and clinically indicated as requiring intensive blood glucose monitoring i.e. finger prick testing at least 8 times per day, as demonstrated on a meter download/review over the past 3 months.
4. Type 1 diabetes and confirmed pregnancy – 12 months in total inclusive of post-delivery period.
5. Type 1 diabetes and unable to routinely self-monitor blood glucose due to disability, requiring carers to support glucose monitoring and insulin management. Carers need to develop their own knowledge and skills in order to support this.
6. Type 1 diabetes and the specialist diabetes multi-disciplinary team determines occupational (e.g. working in insufficiently hygienic conditions to safely facilitate finger-prick blood glucose testing) or psychosocial circumstances that warrant a 6 month trial of FreeStyle Libre® with appropriate adjunct support.
7. Type 1 diabetes and been previously self-funding flash glucose monitoring where those with clinical responsibility for their diabetes care are satisfied that their clinical history suggests that they would have satisfied one or more of these criteria prior to them commencing flash glucose monitoring had these criteria been in place prior to this guidance AND has shown improvement in HbA1c since self-funding.
8. Type 1 diabetes with recurrent severe hypoglycaemia or impaired awareness of hypoglycaemia. NICE suggests that Continuous Glucose Monitoring with an alarm is the standard (FreeStyle Libre® does not have an alarm). However, if the person with diabetes and their clinician consider that a flash glucose monitoring system would be more appropriate for the individual’s specific situation, then this can be considered.

All patients considered for FreeStyle Libre® flash glucose monitoring should be 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 previous attendance, or due consideration given to future attendance, at a Type 1 diabetes 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); or maintain HbA1c target as agreed with specialist in the initial patient contract; or increase to Time In Range as agreed with specialist in the initial patient contract; or improvement in symptoms such as diabetic ketoacidosis or hypoglycaemia; or improvement in psycho-social wellbeing as defined by the specialist diabetes multidisciplinary team at the start of the 6 month trial; 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 no less than 8 times per day and the FreeStyle Libre® sensor is used >70% of the time; and
- The patient has completed regular reviews with the diabetes specialists that initiated the FreeStyle Libre®; 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 for Group 2 bus and lorry drivers.¹

Background

NICE NG17² 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 for Group 2 bus and lorry drivers)¹
- 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 NG18³ 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
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. NHS England agreed criteria for
National Arrangements for funding from 1st April 20194.

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 2)
OR if within 12 months of confirmed pregnancy inclusive of post-delivery period.

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 or a person with Type 1 diabetes unable to routinely self-monitor blood
glucose due to disability, a caregiver aged at least 18 years old must supervise 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 for Group 2 bus and
lorry drivers.

In January 2019 the DVLA requirement changed to allow Group 1 drivers (cars and
motorcycles) to use flash glucose monitoring systems although it must be noted that Group 1
drivers should still carry blood glucose testing equipment as there are times when a
confirmatory finger-prick blood glucose test is required6. The most cost effective choice of test
strip should be prescribed in line with the local health economy formulary6.

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 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 used in 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. Barrier methods to reduce skin reactions to sensor adhesive are not recommended as they may affect the device performance.

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 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 and the NHS England Guidance 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 FreeStyle Libre® and re-establishment of blood glucose testing 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.

It should be noted that ALL patients provided with a FreeStyle Libre® system will also continue to need a supply of blood glucose testing strips for monitoring blood glucose in specific circumstances (e.g. 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
2. NICE NG17. Type 1 diabetes in adults: diagnosis and management. Last updated July 2016. Available at: https://www.nice.org.uk/guidance/ng17
3. 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
5. Central and Eastern Cheshire Medicines Management Team Formulary. Available at: www.centralandeasterncheshireMMT.nhs.uk