Policy for Freestyle Libre® Flash Glucose Monitoring System use in Type 1 Diabetic Adult & Paediatric Patients

NOTE: Not for Primary Care Prescribing.

Hospital Initiation and ongoing supplies only

INTRODUCTION

The FreeStyle Libre® 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 get a result. It can produce a near continuous record of measurements which can be accessed on demand. It can also indicate glucose level trends over time. The FreeStyle Libre® system is indicated for measuring interstitial fluid glucose levels in people (age 4 and older) with diabetes mellitus. The product is classified as a device and received European CE mark certification in August 2014. The sensors may also be read with an appropriate application on a Smart phone which has near-field communication.

This new technology helps to reduce the burden of finger prick blood tests but there is not any evidence available as yet as to whether it reduces complications and long-term outcomes for diabetic patients.

There is not a NICE directive for CCGs to fund this new technology but NICE have undertaken a Medtech innovation briefing which can be found here: https://www.nice.org.uk/advice/mib110

Please note that although Freestyle Libre® can be used in type 2 diabetic patients, use in this patient group is not recommended or supported locally.

EVIDENCE

The main points from the evidence are from 5 studies involving 700 people. This 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). 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.

Patients 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%; $p<0.0001$).

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.

There is limited safety data available on the use of the Freestyle Libre® device. The only published study carried out by Bailey et al reported there were no unexpected adverse device effects reported during the clinical study. Finger prick capillary blood glucose monitoring 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 14 days lifespan of the Freestyle Libre® sensor.

PATIENT PERSPECTIVE

All of the included studies report a high level of user preference for FreeStyle Libre® over 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).

The device may therefore offer some advantages in terms of patient acceptability and quality of life and patients will be pleased at the option to use Freestyle Libre® if it has been found to be suitable for them.

COST-EFFECTIVENESS/AFFORDABILITY

There is currently no UK cost-effectiveness data available for Freestyle Libre® to be able to determine whether this new technology is cost-effective for the NHS. 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 blood glucose test strips.

Impact upon the individual CCGs test strip expenditure will be evaluated further after 12 months.

A year's cost of sensors is £910 per patient. The Freestyle Libre® reader is not available on prescription and will be provided free of charge by the manufacturer.

RECOMMENDATION

Freestyle Libre® is recommended for the following patient groups:

Patients with **Type 1 diabetes mellitus** (DM), aged 4 years and above, or total pancreatic failure who despite intensive specialist input continue to have **poor control** (target HbA1c not achieved or inability to achieve target due to frequent episodes of hypoglycaemia (particularly at night) or disabling fear of hypoglycaemia overnight in children & their carers) of their blood glucose levels and meet one or more of the following:

- Finger prick test at least 8 times per day (and this testing frequency is deemed clinically appropriate) and where the use of Freestyle Libre is likely to bring clinical benefit in terms of HbA1C reduction towards target level.
- Those who meet the current NICE criteria for insulin pump therapy (HbA1c > 68mmol/mol (>8.5%) or disabling hypoglycaemia as described in NICE TA151) where a successful trial of Freestyle Libre® may avoid the need for pump therapy. If the patient ends up requiring a pump, the funding for Freestyle Libre will be reviewed.
- 2 or more hospital admissions with diabetic ketoacidosis or 2 or more severe episodes of hypoglycaemia (per year).
- Those who have recently developed impaired awareness of hypoglycaemia (GOLD score ≥4 for adults & children), when it may be used as a tool in its management. Note that for persistent hypoglycaemia unawareness, NICE recommends continuous glucose monitoring with alarms and Freestyle Libre® does not have that function.
- Those who require third parties to carry out monitoring (e.g. mentally or physically unable to undertake blood glucose monitoring) and where conventional blood testing is not possible.

ALL adult patients should have previously been through an advanced insulin self-management education course such as "Freedom for Life" or equivalent local accredited education programmes to ensure that they are managing their condition to the best of their ability in the past 3 years. This is to ensure that patients are using effective basal bolus insulin self-management with evidence of carbohydrate counting and correction insulin use and yet are still having problematic blood glucose control.

INITIATION AND CONTINUATION

The decision to start FreeStyle Libre® system will only be made by the diabetes consultant. It will be provided by the specialist team and initially on a **6 month trial basis only**. Patients must be able to accurately interpret and act appropriately on bio feedback information from the Libre device. If criteria are met for initiation, patients/carers will be required to sign a contract outlining their commitment to regular scans, their use in self-management and attendance at training and appointments as well as leading as healthy a lifestyle as possible. Patients also need to understand that use will only be continued on the NHS at the discretion of the diabetes specialist team if there is a sustained improvement in the following patient outcomes whilst they are using the device:

- Reduction in HbA1C of at least 0.5% within 6 months
- Reduction in blood glucose test strips (BGTS) use, (ideally this would be ≤4 /day). **Note:** Commissioners would expect patients to receive clinical benefit from this technology rather than test strip use reduction alone.
- Reductions in severe hypoglycaemia episodes (if applicable)
- Reductions in episodes of diabetic ketoacidosis (if applicable)
- Reductions in admissions to hospital &/or ambulance call-outs (if applicable)
- Patients/carers must regularly scan their sensor regularly every day (ideally this would be ~4 /day) and use the results in their self-management. If patients/carers are not using their sensors every day, NHS funding for Freestyle Libre will be removed.

NOTE: These criteria do NOT apply to those patients who are using Freestyle Libre due to not having mental (e.g. learning disabilities) or physical capacity (e.g. manual dexterity problems which require a carer to do finger prick testing on their behalf) to undertake blood glucose monitoring.

The clinical effectiveness of Freestyle Libre will be assessed at 6 months to ensure that it is only continued in those patients where benefits listed above have been achieved. If benefits are achieved at this stage, on-going effectiveness will then be re-assessed on a 6 to 12 month basis.

Patients should be told that NHS provision of Freestyle Libre® will be withdrawn if these criteria are not met at each review. All of this information will be conveyed to the patient by using the patient contract.

Full details of the expected outcomes of treatment must be documented, and the results also communicated to the GP.

It is expected that the most cost effective choice of blood glucose test strip is prescribed in line with the NHS Wiltshire/Swindon/BaNES test strip guidance (found here: https://prescribing.wiltshireccg.nhs.uk/prescribing-guidance-by-bnf-chapter/endocrine) to use with the Freestyle Libre® device.

Patients currently self-funding will be reviewed by the specialist service at their next planned specialist appointment and only if they meet the criteria for NHS funding, will the specialist initiate and supply the sensors and reader device.

FREESTYLE LIBRE® AND TEST STRIP USE FOR DRIVING

In the IMPACT trial of Freestyle Libre®, BGTS usage averaged 0.5 strips per day. As the device measures interstitial glucose levels and not capillary blood glucose, measurements will be slightly delayed and users will still need to perform finger-prick blood tests during periods of illness, rapidly changing interstitial glucose levels, where the symptoms do match the reading and prior to and during driving to meet current DVLA requirements.

As Flash glucose testing is not currently accepted by the DVLA, it would not be an appropriate choice for those with a high frequency of blood glucose testing as a result of their driving requirements. Such patients would not be able to reduce their use of blood glucose test strips enough to make this technology affordable.

SUPPLY & COMMISSIONING ARRANGEMENTS

Local provider trusts will be required to supply eligible patients with their Freestyle Libre® sensors when they see them at their regular out-patient appointments whilst the 1 year audit/trial is taking place. In order to reduce waste, patients should not be given large amounts of supplies (e.g. 6 months' worth) in one go and so arrangements will need to be made to allow patients to collect further supplies of the sensors in-between appointments. During the 1 year trial, commissioners do not expect GPs/primary care to be asked to prescribe the sensors so the sensors will be dealt with locally on the formularies as a RED traffic light status.

Provider trusts will be able to charge commissioners for the sensors supplied via pass-through payment for adult patients and paediatric specialists will retain their own budget to manage.

The CCGs will review activity related to provision of Freestyle Libre® using audit data supplied by provider trusts, which will inform further policy development after the first year of local use.

PROVIDER REPORTING TO COMMISSIONERS

Specialist teams must audit and monitor outcomes in any patients started on the new system; information gathered will inform a review of this policy in 12 months' time.

Provider trusts will be expected to provide commissioners with a quarterly audit report to include numbers of patients initiated on Freestyle Libre, and for each patient, reduction in test strip use, change in HbA1c and any reduction in the number of hypoglycaemia episodes, Diabetic Ketoacidosis episodes, ambulance call-outs and hospital admissions. Also, the number of patients who have stopped after an unsuccessful trial of Freestyle Libre should be reported to the commissioners.

The ABCD standard audit forms (https://abcd.care/launch-abcd-nationwide- freestyle-libre-audit) should be used to collect the required data and a report shared with commissioners at 6, 9 and 12 months so that an informed review of the policy can take place. Providers will also be asked to report the number of extra appointments made as a result of Freestyle Libre® use and whom the appointments are with (Consultant or Diabetic Specialist Nurse).

If audit data is not received by the commissioners, no further patients will be funded.

CLINICAL PRIORITIES FOR OUR CCG

The use of Flash Glucose Monitoring systems for any **other** indication is **low priority**.

The CCG is aware that this is an evolving field and that more evidence is being collected. Consequently this statement will be scheduled for further review in early 2019.

The CCG have a duty to prioritise spending of a finite resource locally and made a decision which it felt gave the most equitable and effective use of investment.

This policy will be reviewed in the light of any relevant national guidance that is published.

Further information:

1.) Regional Medicines Optimisation Committee FreeStyle Libre Position Statement 1st November 2018 https://www.sps.nhs.uk/articles/regional-medicines-optimisation-committee-freestyle-libre-position-statement/

2.) Gold AE[1], MacLeod KM, Frier BM. Frequency of severe hypoglycemia in patients with type I diabetes with impaired awareness of hypoglycemia. Diabetes Care. 1994 Jul;17(7):697-703. https://www.ncbi.nlm.nih.gov/pubmed/7924780