HERTFORDSHIRE MEDICINES MANAGEMENT COMMITTEE (HMMC)
FREESTYLE LIBRE/LIBRE 2® FOR BLOOD GLUCOSE MONITORING IN DIABETES

RECOMMENDED FOR RESTRICTED USE (AMBER INITIATION)

Name:	What it is	Date decision last revised	Decision status	NICE / SMC Guidance
FreeStyle Libre® & Libre 2®	Flash glucose monitoring system	February 2021*	Final	NICE – Medtech innovation briefing only SMC – No decision

* September 2020, duration of specialist supply reduced from 6 months to 2 months prior to transfer to GP prescribing for **new** patients; **previous self-funders** – GPs to take on prescribing following specialist review/confirmation that the patient meets both NHS England initiation and continuation criteria.
December 2020, updated to include additional NHSE approved cohort (learning disabilities).
February 2021, updated to include approval for use of **FreeStyle Libre 2®** for new and existing patients:

- **New patients** – no change to approval or supply process (see below)
- **Existing patients** – upgrade to **FreeStyle Libre 2®** to be led by diabetes specialists. See Herts guidance on upgrading to FreeStyle Libre 2® for further details, available at: LINK

HMMC Recommendation:

FreeStyle Libre/Libre 2® is recommended for restricted use as an option for: (1) patients who satisfy the NHS England funding criteria, available at: https://www.england.nhs.uk/publication/flash-glucose-monitoring-national-arrangements-for-funding-of-relevant-diabetes-patients/ . See Appendix 1 for the full criteria; (2) *existing* patients funded under the previously approved HMMC guidelines who met agreed criteria in accordance with the East Of England Priorities Advisory Committee (PAC) recommendations.

The NHS England funding arrangements were provided for a 2 year period in April 2019, after which, CCGs will make a decision on whether to continue funding.

PRIMARY CARE INITIATION IS NOT RECOMMENDED.
For new patients, FreeStyle Libre/Libre 2® is to be initiated, managed and the first 2-months' supply provided by a provider Trust consultant led specialist diabetes team only. Previous self-funders – GPs to take on prescribing following specialist review/confirmation that the patient meets both NHS England initiation and continuation criteria.

The following applies:
Specialist diabetes team are required to:

- complete Blueteq prior approval application forms for each patient and submit to CCG
- complete patient contract/agreement form with each patient
- provide appropriate training and advice to patients on use of FreeStyle Libre/Libre 2®
- monitor patients to confirm appropriate use and benefit
- stop treatment where FreeStyle Libre/Libre 2® is not being used appropriately and/or treatment goals have not been achieved.

Expected review schedule by specialists (for new patients) would be 2-4 weeks (by telephone), 2-3 months and 5-6 months. Funding arrangements per patient will be reviewed at 6 months and then annually. **Continuation of FreeStyle Libre/Libre 2® after the 6-month review for all patients is contingent upon evidence that the patient: (1) has met NHS England's conditions for funding, and (2) that on-going use of the Flash Glucose Monitoring is demonstrably improving an individual's diabetes self-management (see Appendix 1). This will be subject to prior approval by the CCG (via Blueteq).**

For patients who are newly started on FreeStyle Libre/Libre 2®, the specialist diabetes team will contact GP practices when patients are initiated on treatment (this will include a request for GPs to take over prescribing after an initial 2 month supply). The specialist diabetes team will also contact GP practices after the 6 month review (for new patients **and** previous self-funders) to confirm if FreeStyle Libre/Libre 2® has been discontinued or is to be continued. **There will be a continued need for GP practices to prescribe blood glucose and ketone testing strips, although the quantities required may be reduced.** The specialist diabetes team will advise on product choice and estimated quantities to prescribe.

The expectation is that patients being considered for FreeStyle Libre/Libre 2® as they are part of the agreed patient groups will already be known to, and under the care of a specialist diabetes team. GPs should only consider referral of patients to specialist diabetes services where patients are within the agreed patient groups and are not already under the care of the specialist service.

See **Appendix 2** for summary of process for initiation and supply of FreeStyle Libre/Libre 2® in primary and secondary care.

A Frequently asked Questions document for patients regarding recommendations for FreeStyle Libre/Libre 2® in Hertfordshire can be found on the following link.

Background information

- FreeStyle Libre/Libre 2® is a flash glucose monitoring system which allows people with diabetes mellitus (age 4 and older) to monitor glucose levels using interstitial fluid levels rather than capillary blood glucose from finger prick testing.
- It consists of a handheld reader and a sensor (size of a £2 coin), which is sited on the back of the arm. When the reader unit is passed over the sensor, the reader shows a reading. The sensor lasts for up to 14 days and then needs to be replaced. The reader can show a trace for the last eight hours and displays an arrow showing the direction the glucose reading is heading. Flash glucose monitoring is not the same as continuous glucose monitoring (CGM).
- A finger-prick test using a blood glucose meter is still required with FreeStyle Libre® during times of rapidly changing glucose levels when interstitial fluid glucose levels may not accurately reflect blood glucose levels e.g. acute illness such as Influenza, diarrhoea and vomiting, or if hypoglycaemia or impending hypoglycaemia is reported, or the symptoms do not match the system readings. Because of its accuracy, there's no need for finger-prick testing when using the FreeStyle Libre 2® system - even when glucose is low, falling or rapidly changing. However, finger pricks are required if glucose readings and alarms do not match symptoms or expectations.
- The FreeStyle Libre 2® system also offers three optional real-time alarms for those who need them. There is a Low Glucose Alarm, High Glucose Alarm and Signal Loss Alarm.
- The DVLA has updated the guidance on glucose testing prior to driving, which now permits the use of real time glucose monitoring system e.g. FreeStyle Libre/Libre 2® **for group 1 drivers only. CLICK HERE FOR FULL INFORMATION** as finger prick tests are still required (even for group 1 drivers) under certain circumstances.

Assessment against Ethical Framework

Evidence of Clinical Effectiveness

- One open label manufacturer sponsored RCT involving 224 patients with type 2 diabetes treated with insulin for at least 6 months. There was no difference in change of HbA1c between intervention (FreeStyle Libre®) and control (self-monitoring of blood glucose) -3.1± 0.75mmol/mol [-0.29 ± 0.07%(mean ± SE) and -3.4 ± 1.04 mmol/mol [0.31 ±0.09%] respectively; p = 0.8222. In participants, younger than 65 years, the drop in HbA1c was more pronounced in the intervention group compared with controls [-5.7 ± 0.96 mmol/mol, (adjusted mean ± SE) (-0.53 ± 0.09%) and -2.2 ± 1.31 mmol/mol (-0.20 ± 0.12%), respectively; p = 0.0301]. A significant interaction between treatment group and age was observed for change in HbA1c (p = 0.0017).
- One multi-centre, manufacturer sponsored non-masked RCT involving 241 adult patients (aged 33-57) with well controlled type 1 diabetes. Mean time in hypoglycaemia changed from 3·38 h/day at baseline to 2·03 h/day at 6 months (baseline adjusted mean change −1·39) in the intervention group, and from 3·44 h/day to 3·27 h/day in the control group (−0·14); with the between-group difference of −1·24 (SE 0·239; p<0·0001). Several secondary outcomes were also reported. HbA1c concentrations in the intervention group were essentially unchanged compared with the control group.
- Three studies reported on 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.
- According to real-world results of the Association of British Clinical Diabetologists (ABCD) audit of the FreeStyle Libre® system (published July 2020), people with type 1 diabetes who use the FreeStyle Libre® system show significant improvements in glycaemic control, haemoglobin AIc (HbA1c) levels and awareness of hypoglycaemia. They are also much less likely to utilise healthcare resources as a result of improved management of their diabetes. The authors looked at data from over 10,000 FreeStyle Libre® users from 102 NHS hospitals in the UK. To date, there had been no comprehensive, real-world, large population-based data sets looking at the impact of FreeStyle Libre on multiple aspects of diabetes care.
  In this study, data from the nationwide audit for the FreeStyle Libre® system were analysed to assess the patterns of use of FreeStyle Libre® and to study its effect on glycaemic control, hypoglycaemia, diabetes-related distress, and hospital admissions due to hypoglycaemia and hyperglycaemia / diabetic ketoacidosis. Baseline data were available for a total of 10,370 FreeStyle Libre® users.
  For those patients with over seven months of follow-up data, the following outcomes were observed:
  - A significant reduction in HbA1c from 67.5 mmol/mol (8.3%) to 62.3 mmol/mol (7.9%) (data for 3,182 people with diabetes - with an even greater reduction in those who had high HbA1c levels before they started using FreeStyle Libre®. In addition, the more people engaged with the management of their diabetes, by using the technology and scanning more frequently, the greater the HbA1c reduction.
  - A significant improvement in patient's awareness of impending hypoglycaemia measured by the Gold score (data for 2,801 patients). Over half of people (53%) with impaired hypoglycaemia awareness at the start of the audit had regained awareness at follow-up.
  - A reduction in patient reported hypoglycaemic events: 85% said that they were able to reduce the frequency of

hypoglycaemia; 80% stated that they were able to reduce the amount of time in hypoglycaemia; and 75% reported a reduction in nocturnal hypoglycaemia.
  - A reduction in diabetes distress – feeling overwhelmed by the demands of living with diabetes and/or a feeling of failing with their diabetes routine (data for 2,532 people with diabetes).
  - A significant reduction in paramedic callouts and hospital admissions due to hypoglycaemia and hyperglycaemia / diabetic ketoacidosis at seven and a half months follow-up, compared to 12 months before FreeStyle Libre® use (data for over 1,900 people with diabetes).

Safety:

- Most common adverse events were sensor related including insertion site allergy, oedema, erythema, rash and itch.

Cost of treatment and Cost Effectiveness

- The gross cost of each sensor is £35.00. In 2019/20 CCGs were reimbursed (by NHS England) £28.56 for each sensor prescribed (on the basis of prescribing data supplied by the Business Services Authority (BSA) **i.e. primary care prescribing only**. The NHS England criteria are estimated to represent up to 20% of the type 1 diabetes population. The NHS England reimbursement amount has been offset by modelling that, prior to using flash glucose monitoring, patients can be expected to have been using blood glucose testing strips, representing a cost to the CCG that will no longer be incurred. The savings from two testing strips per day have therefore been built into the reimbursement level.
- Maximum NHSE CCG reimbursement levels 2019/20:

CCG	No. of patients with Type 1 Diabetes	20% of Type 1 patients	Implied total CCG reimbursement (£)
HERTS VALLEYS CCG	2,610	522	**377,604**
EAST AND NORTH HERTFORDSHIRE CCG	2,710	542	**392,072**

- No studies of cost-effectiveness available.
- NICE Medtech Innovation Briefing for FreeStyle Libre® states that the resource impact of the product is uncertain and will depend upon the extent to which improved glucose control translates into fewer complications, reduced emergency admissions and less use of glucose test strips.
- Annual Cost of FreeStyle Libre/Libre 2® is £912 (for sensors only). The company may supply the handheld reader free of charge.
- In relation to diagnostic costs, patients put on FreeStyle Libre/Libre 2® would have to reduce finger prick testing by at least 10 tests a day for the technology to be cost neutral (using local data).

The needs of the population

- The needs of the population appear to be low as there is an alternative mode of measurement (finger pricking test). However, NHS England have agreed to reimburse CCGs for the ongoing costs of FreeStyle Libre/Libre 2® for patients who meet their funding criteria. Patients who fulfil these criteria will have an expectation for funding.
- FreeStyle Libre/Libre 2® measures glucose levels from a sensor applied to the skin. This is an alternative to finger prick testing that may be preferable to some patients (Note: tests to meet DVLA requirements [in certain circumstances] and during times of illness or rapidly changing glucose levels will still need to be conducted by finger pricking).
- Users would need support and training from a clinician who is familiar with how to use FreeStyle Libre/Libre 2® and interpret its readings.

The needs of the community

- The needs of the community may be large as a large numbers of patients have insulin dependent diabetes. The impact on the health economy appears to be high as FreeStyle Libre/Libre 2® has a high cost and its cost effectiveness is uncertain.
- In 2019/20 NHS England will reimburse CCGs for each set of sensors prescribed for up to 20% of their type 1 diabetes population.
- There will be costs associated with continuing to fund HMMC cohorts not covered by NHSE guidance.

Equity: No impact anticipated. There is an expectation that funding will be approved in line with NHSE criteria.

Policy Drivers

- NHS England flash glucose monitoring funding arrangements https://www.england.nhs.uk/publication/flash-glucose-monitoring-national-arrangements-for-funding-of-relevant-diabetes-patients/
- HMMC Freestyle Libre® guidance for blood glucose monitoring in diabetes (December 2017) (in accordance with the East Of England Priorities Advisory Committee [PAC]) recommendations.
- NICE – No NICE TA recommendations. NICE guidance in relation to diabetes does not currently support the routine use of interstitial fluid to monitor blood glucose and recommends that finger pricking and capillary blood should be used routinely until more evidence is available. Continuous Glucose Monitoring, which also uses interstitial fluid is recommended as an option in certain circumstances, but is not recommended for routine use. There is a NICE Medtech innovation briefing document on FreeStyle Libre® to support the decision making process.
- SMC and AWMSG – No decision.
- Regional Medicines Optimisation Committee - RMOC (North) FreeStyle Libre® Position Statement - Lists cohorts that prescribing committees may wish to consider and audit for response https://www.sps.nhs.uk/articles/regional-

medicines-optimisation-committee-freestyle-libre-position-statement/ .

- Association of British Clinical Diabetologists (ABCD) – lists suggestions that prescribing committees may wish to consider and audit for response https://abcd.care/ .

Implementability

Work will be completed with West Hertfordshire Hospitals NHS Trust, East and North Hertfordshire NHS Trust and Hertfordshire Community NHS Trust diabetes specialists and pharmacy departments to put in place appropriate arrangements for the implementation of the local recommendations.

References

- NICE Medtech innovation briefing (MIB110): FreeStyle Libre® for glucose monitoring. Published date: 3rd July 2017. https://www.nice.org.uk/advice/mib110
- Deshmukh H, Wilmot EG, Gregory R, Barnes D, Narendran P, Saunders S, Furlong N, Kamaruddin S, Banatwalla R, Herring R, Kilvert A. Effect of Flash Glucose Monitoring on Glycemic Control, Hypoglycemia, Diabetes-Related Distress, and Resource Utilization in the Association of British Clinical Diabetologists (ABCD) Nationwide Audit. Diabetes care (July 2020):dc200738. Available at: https://care.diabetesjournals.org/content/early/2020/07/03/dc20-0738

Appendices

Appendix 1 - Criteria for NHS England Flash Glucose Monitoring Reimbursement:

1. People with Type 1 diabetes
   OR with any form of diabetes on hemodialysis and on insulin treatment
   who, in either of the above, are clinically indicated as requiring intensive monitoring >8 times daily, as demonstrated on a meter download/review over the past 3 months
   OR with diabetes associated with cystic fibrosis on insulin treatment
2. Pregnant women with Type 1 Diabetes - 12 months in total inclusive of post-delivery period.
3. People with Type 1 diabetes unable to routinely self-monitor blood glucose due to disability who require carers to support glucose monitoring and insulin management.
4. People with Type 1 diabetes for whom the specialist diabetes MDT determines have occupational (e.g. working in insufficiently hygienic conditions to safely facilitate finger-prick testing) or psychosocial circumstances that warrant a 6-month trial of Libre with appropriate adjunct support.
5. Previous self-funders of Flash Glucose Monitors with Type 1 diabetes 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 use of Flash Glucose Monitoring had these criteria been in place prior to April 2019 AND has shown improvement in HbA1c since self-funding.
6. For those with Type 1 diabetes and recurrent severe hypoglycemia or impaired awareness of hypoglycemia, NICE suggests that Continuous Glucose Monitoring with an alarm is the standard. Other evidence-based alternatives with NICE guidance or NICE TA support are pump therapy, psychological support, structured education, islet transplantation and whole pancreas transplantation. 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.
7. People with Type 1 diabetes or insulin treated Type 2 diabetes who are living with a learning disability and recorded on their GP Learning Disability register.

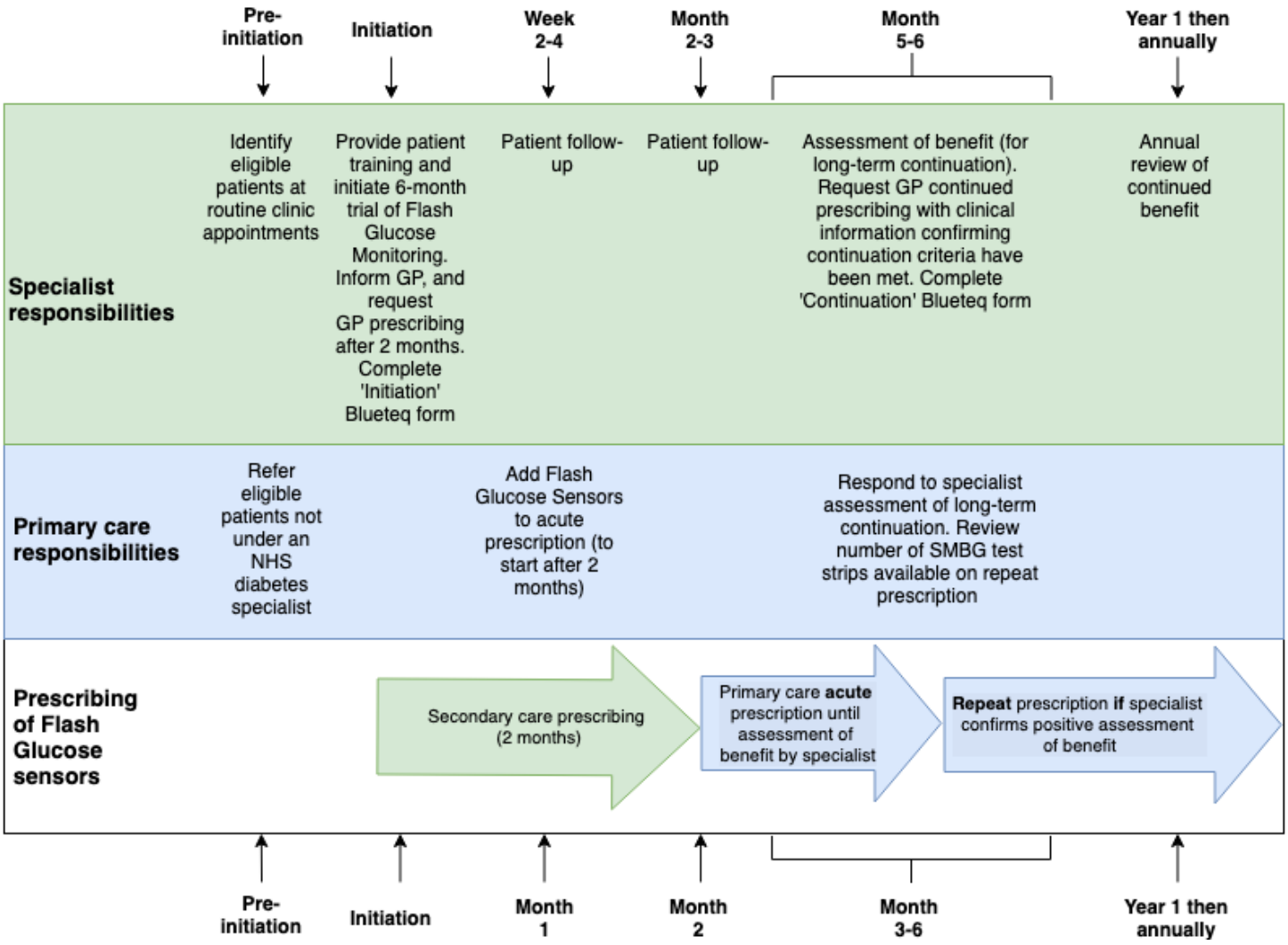
Other requirements:

1. Education on Flash Glucose Monitoring has been provided (online or in person).
2. Agree to scan glucose levels no less than 8 times per day and use the sensor >70% of the time.
3. Agree to regular reviews with the local clinical team.
4. Previous attendance, or due consideration given to future attendance, at a Type 1 diabetes structured education programme (DAFNE or equivalent if available locally).

Note:

Continuing prescription for long-term use of Flash Glucose Monitoring-post initial 6 months- would be contingent upon evidence of agreeing with the above conditions and that on-going use of the Flash Glucose Monitoring is demonstrably improving an individual's diabetes self-management- for example improvement of HbA1c or Time In Range; improvement in symptoms such as DKA or hypoglycaemia; or improvement in psycho-social wellbeing.

Appendix 2 - Summary of process for initiation and supply of FreeStyle Libre/Libre 2®



(Process map [with adaptations] used with the permission of NCL CCG)