THE SHEFFIELD AREA PRESCRIBING GROUP

Position Statement for Prescribing of Freestyle Libre 2
In Type 1 Diabetes, except where otherwise stated

Date of approval: April 2019
Date amended: January 2021
Date of review: January 2023

Overview

Freestyle Libre 2 is a flash glucose sensor device that measures **interstitial glucose. Users have a disposable sensor that is worn on the upper arm; this has a microfilament that is inserted under the skin. A reader / phone, when passed over the sensor, displays interstitial glucose levels. The reader / phone needs to be passed over the sensor at least every 8 hours to get continuous glucose readings. Each sensor lasts for two weeks.

From 1st January 2021 a new Freestyle Libre 2 flash glucose sensor is available to be prescribed in primary care. It has an additional alarm function to help avoid hypoglycaemic and hyperglycaemic episodes. It is envisaged that all patients will be transferred over from FSL to FSL 2, a letter has been sent to all patients from the Specialist teams as patients using a reader will require a new compatible reader. Those patients using their smart phones to read the sensor need to ensure the app is updated.

Using Freestyle Libre 2 should reduce the frequency of finger prick monitoring to measure blood glucose levels, however blood glucose levels should still be taken.

- When interstitial glucose levels are rapidly changing (due to the time lag** between blood glucose and interstitial glucose levels).
- When scanned glucose results do not meet with the user's symptoms.
- To use the bolus calculator function.
- Group 2 drivers must continue to use finger prick testing for the purposes of driving.

Criteria, which are not exclusive, from https://www.england.nhs.uk/wp-content/uploads/2019/03/National-arrangements-for-funding-of-relevant-diabetes-patients-June-2020-Updated-final.pdf have been used to aid patient selection, which should be made by the specialist and as such it is classified as **amber in the traffic light drug list.** Freestyle Libre 2 should **not** be initiated in primary care, but prescribing may be continued after the patient has been commenced and received training on the device in secondary care. The continued benefits of using flash glucose monitoring should be assessed and stopped if the criteria are not met. Eligible patients should receive no more than two sensors each month (28 days) on the NHS.

Below are the locally agreed criteria for patient selection for adults and children. Patients who do not fit these criteria but who wish to use the Freestyle Libre 2 can purchase the device and sensor from Abbott directly. Note: the criteria apply to patients with Type 1 diabetes, except when otherwise stated.

**Interstitial glucose levels are not quite the same as blood glucose levels, glucose levels in the blood rise and fall ahead of glucose levels in interstitial fluid.

Children and Young People (under 19 years of age)

Criteria

Paediatric patients who meet the criteria outlined within the national guideline developed by the Association of Children's Diabetes Clinicians (ACDC) will be eligible for Freestyle Libre 2 on the NHS. The Executive summary can be found at: http://www.a-c-d-c.org/wp-content/uploads/2012/08/CGM-FGS-Executive-Summary-April-2017.pdf

- Continuous glucose monitoring (CGM)/Freestyle Libre 2 can be considered for children on insulin pump therapy or multiple daily injections.
- CGM/Freestyle Libre 2 can be considered for improving diabetes control in children and young people by reducing HbA1c and/or reducing the time spent in hypoglycaemia, with any HbA1c <10% (<85 mmol/mol).
- CGM/Freestyle Libre 2 may be used where fear of hypoglycaemia provokes clinically significant anxiety and is a barrier to good control.
- Frequent hypoglycaemia and in nocturnal hypoglycaemia. Note - Freestyle Libre 2 may be considered where hypoglycaemia or hypoglycaemia unawareness is a problem but in many circumstances a full CGM system with alarms may be more suitable.
- The Freestyle Libre 2 may be considered in certain circumstances where capillary blood glucose monitoring within the school or nursery environment is challenging and adversely affecting control (note – training will be given to the school).
- Continuous CGM/Freestyle Libre 2 should be considered for exercise in children and young people in the following circumstances:
    - For those competing or exercising regularly. It can be used to optimise carbohydrate and insulin adjustment before, during and after exercise to maximise the effect of exercise on improving diabetes control and ensure that sporting performance is optimised.
    - For adolescents trying to lose weight but fearful of the hypoglycaemic effects of exercise.
    - For those who have had a severe episode of hypoglycaemia following sporting activity and cannot resume activity.
    - For those in whom there is concern regarding overcompensation with additional carbohydrate for activity.
    - Those involved in high endurance sporting activities where it is difficult to test blood sugar.
    - For those where exercise results in unpredictable hypoglycaemia.
- Where clinically appropriate, Freestyle Libre 2 may be considered in patients doing more than 6 capillary blood tests daily as likely to be cost neutral, as demonstrated on a meter down load/review over the past 3 months.

In addition, patients meeting the criteria as listed in the NHSE national arrangements for flash glucose monitoring reimbursement, including:

- Diabetes associated with cystic fibrosis on insulin treatment.
- Any form of diabetes on haemodialysis and on insulin treatment where monitoring blood glucose 8 or more times a day as demonstrated on a meter download/review over the past 3 months.
- Patients 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.
- When determined by the specialist diabetes MDT, occupational (e.g. working in insufficiently hygienic conditions to safely facilitate finger prick testing) or psychosocial circumstances that warrant a 6 month trial of Freestyle Libre 2 with appropriate adjunct support.

In order to maximise benefit patients must use the device at least 70% of the time (5/6 days a week minimum). Ideally it should be used continuously.

The use of Freestyle Libre 2 should be used to bring about clinical benefits. Whilst a reduction in capillary glucose testing would be expected, capillary blood glucose testing will still be needed in certain situations (see above). The use of the Freestyle Libre should not be seen as a direct alternative or replacement for capillary glucose testing.

All patients will have a defined trial period of the Freestyle Libre 2 (see criteria for stopping below); attendance at specific teaching/training sessions is a key pre-requisite of NHS provision of Freestyle Libre 2 systems. Primary care will be asked to prescribe after training has been received and the trial period completed. The specialist will continue to monitor effectiveness and advise the GP on continued need.

Criteria for stopping in children and young people

Withdrawal – Freestyle Libre 2 funding should be withdrawn in the following situations:

- After 1 month if:
  - CGM has not been used 70% of the time – 5/6 days a week minimum
  - Family have not attended all 4 education step 1,2,3,4 sessions unless extenuating circumstances

- At 3 months if:
  - Not worn for at least 5 days a week.
  - No improvement in any of the following factors
    - Glycaemic control – HbA1c improved by >0.5% if it was >7.5% (58 mmol/mol) at start of CGM therapy or time in range
    - No improvement in scores on fear of hypoglycaemia scales where CGM was introduced for anxiety
    - No reduction in symptoms, e.g. DKA or frequency of hypoglycaemia – particularly nocturnal hypoglycaemia (assessed from CGM download)
    - No improvement in psycho-social wellbeing

Adults

Criteria

A. Type 1 diabetes patients and willing to engage with secondary care team on a regular basis, as evidenced by regular appointment attendance, diary completion, baseline and follow-up assessment of HbA1c etc. Ongoing self-care and regular review including all 9 care processes being up to date (see appendix).

    - PLUS one or more of the following:

- Patients on basal bolus or pump therapy with sub optimal control i.e. HbA1c > 8.5% (69mmol/mol), DAFNE trained (or due consideration given to future attendance at DAFNE training) and engaging in self-management, i.e. testing on average 4 times a day for 3 months, as evidenced by a meter download.
- Planning pregnancy (during pregnancy or post-partum real-time CGM, not Freestyle Libre 2 should be used)
- Frequent episodes of hypoglycaemia / diabetic ketoacidosis needing DSN (diabetes specialist nurse) support.
- Palliative patients who require carers to support glucose monitoring and insulin management
- Patient monitoring blood glucose 8 or more times a day as demonstrated on a meter download/review over the past 3 months
- 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.
- Occupational (e.g. working in insufficiently hygienic conditions to safely facilitate finger-prick testing), as determined by the specialist.
- When determined by the specialist diabetes MDT, (e.g. working in insufficiently hygienic conditions to safely facilitate finger prick testing) or psychosocial circumstances that warrant a 6 month trial of Freestyle Libre 2 with appropriate adjunct support.

B. Any form of diabetes on haemodialysis and on insulin treatment where monitoring blood glucose 8 or more times a day, as demonstrated on a meter download/review over the past 3 months

C. Diabetes associated with cystic fibrosis on insulin treatment

D. Patients with disabilities (learning or physical) i.e patients with Type I diabetes or insulin treated Type II diabetes who are living with a learning disability and recorded on their GP learning disability register.

Groups not suitable

- Individuals with total hypoglycaemia unawareness. 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.
- Individuals with HbA1c >85mmol/mol (indicating not giving insulin regularly each day)
- Women with type 1 diabetes who are pregnant, instead real-time CGM should be used.

Primary care prescribing advice

- Secondary care will provide the reader and one sensor; primary care will be asked to prescribe further sensors after two weeks. GPs will be asked to supply no more than 6 sensors (only a 3 month supply) at a time, i.e. until the next review at STH
- The patient will be assessed by secondary care every 3 months for the first 12 months for continuation of the Freestyle Libre 2 prescription; after 12 months the GP to review 6 monthly

  The following should be reviewed:

  - Incidence of hypoglycaemic and DKA episodes
  - 9 care processes are up to date
  - HbA1C and hypoglycaemia levels - if the target has not been met stop Freestyle Libre 2 and inform secondary care

Patients who report that their reader is faulty please ask them to contact Abbott directly on: 0800 170 1177. In addition, patients who are changing to FSL 2 and who use a reader will need to contact Abbott for a replacement and provide the serial number of their current FSL reader.

Criteria for stopping

- Patients with a baseline HbA1c **<70mmol/mol** - if a 5mmol/mol drop by 3 months is not achieved **or** a significant reduction in time spent in hypoglycaemia is not achieved. If reduction not maintained at 6 months.
- Patients with a baseline HbA1c **≥70mmol/mol -** if a 10mmol/mol drop by 3 months is not achieved, or a significant reduction in time spent in hypoglycaemia is not achieved. If reduction is not maintained at 6 months.
- For those previously self-funding: blood glucose levels - not at target for the majority of time, HbA1c >58mmol/mol or >10% of readings under 4mmol/L
- Not up to date with the 9 care processes
- No improvement in DKA episodes

This position statement was developed in conjunction with diabetes specialists at STHFT and SCHFT and approved by APG: *April 2019, Interim review Sept 2019* . Updated January 2021 and approved by APG February 2021.
Review January 2023

Appendix - The nine processes of care;

- Weight
- Blood pressure
- Smoking status
- HbA1c
- Urinary albumin
- Serum creatinine
- Cholesterol
- Eye examinations
- Foot examinations

Further supporting information

Community pharmacies need to order Freestyle Libre 2 directly from Abbott, see link to the dedicated web portal - www.Freestylediabetes.co.uk/pharmacy
An account needs to be set up (takes 24 hours), then ordered stock is delivered free of charge directly to them on the next working day.

MHRA alert (January 2019)
Freestyle Libre: use of barrier methods to reduce skin reactions may affect device performance
https://www.gov.uk/government/news/alert-to-users-of-freestyle-libre-flash-glucose-monitoring-system-regarding-skin-reactions-to-sensor-adhesive

NHS England Flash Glucose Monitoring: National Arrangements for Funding of Relevant Diabetes Patients (June 2020)
https://www.england.nhs.uk/wp-content/uploads/2019/03/National-arrangements-for-funding-of-relevant-diabetes-patients-June-2020-Updated-final.pdf