NHS
Kent and Medway
Clinical Commissioning Group

Flash Glucose Monitoring System
Treatment Pathway

About Freestyle Libre system

The FreeStyle Libre (FSL) 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 glucose measurements which can be accessed on demand.

As an alternative to using the reader, the sensor can be scanned with a mobile device capable of near-field communication (NFC) and on which the LibreLink companion app has been installed. Further details on the use of the device can be found here.

Treatment with Freestyle Libre

Patients who meet the set criteria for FSL will be initiated by a diabetes specialist in secondary care ; subsequent prescriptions will be through the patient's GP practice. **Primary care should not initiate FSL 1or 2.** (See Appendix 2 for a Quick Reference Guide for Primary Care Clinicians)

Patients not currently under the secondary care diabetes specialist service and potentially meet initiation criteria, should be referred to the relevant secondary care diabetes specialist service.

FSL will only be initiated on a 6 month trial basis (maximum 9 months) whereby at 6 to 9 months they must meet continuation criteria for ongoing NHS funding.

GPs will be notified in writing at 6-9 months whether patients should continue treatment with FSL or to stop if treatment criteria are not being fulfilled.

It is expected that demand/frequency of supply of adjunct blood glucose testing strips will be reduced following initiation of FSL. This will also be communicated in the letter sent from the secondary care appointment.

NHS England advises: To manage workload & product supply, Libre 2 will be offered to patients who meet the eligibility criteria for Flash at their next routine appointment with their diabetes healthcare professional. In the current climate, we respectfully request that patients wait until their next routine appointment with their diabetes healthcare team in 2021 to enquire about the FreeStyle Libre 2 system. Please click here for more information. This change can either be at the request from secondary care or by clinical judgement in primary care setting. For more information for healthcare professionals in Freestyle Libre please click here.

Eligibility criteria

Diabetic patients who meet one of the following criteria can be considered for FSL.

- People with Type 1 diabetes
  OR with any form of diabetes on haemodialysis 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
- Pregnant women with Type 1 Diabetes - 12 months in total inclusive of post-delivery period.
- 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.

Approved by: JPC, KMMOC, Clinical Cabinet
Approved Date: Clinical Cabinet 01/04/2021
Review Date: April 2023

- 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 FSL with appropriate adjunct support.
- 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.
- For those with Type 1 diabetes and recurrent severe hypoglycaemia or impaired awareness of hypoglycaemia, 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.
- People with Type 1 diabetes or insulin treated Type 2 diabetes who are living with a learning disability and recorded on the GP Learning Disability QOF register **(NEW 2020).**

Other requirements

- Previous patient attendance, or due consideration given to future attendance, at a Type 1 diabetes structured education programme (DAFNE or equivalent if available locally) if applicable.
- Patient/carer must complete a patient/prescriber agreement form to ensure that all parties are clear regarding aims of treatment and targets to be achieved or maintained.
- Patients will be issued with a starter pack which contains the reader and one sensor. The specialist team will then write to the GP to request ongoing prescribing of FSL. GPs should only continue the sensors if there is a signed patient agreement form and clear written communication outlining the criteria that the patient has met from the specialist team.
- Education on Flash Glucose Monitoring should be provided (online or in person).
    - The specialist team will provide training and/or training materials on the use of FreeStyle Libre
    - There is a range of education and support available for both patients and healthcare practitioners from Abbott, including:
        - FreeStyle Academy – Flash 2 Alarms Functionality module
        - Webinars – both on-demand and live webinars highlighting the new features of Flash 2
        - Website information and the FreeStyle Customer Careline
        - Print materials provided to HCPs including: Patient Education Booklet, FreeStyle LibreLink How to Guide, LibreView Guide and more
    - Tutorial videos are available https://www.freestylelibre.co.uk/libre/help/tutorials.html
- Patient must agree to scan glucose levels no less than 8 times per day and use the sensor >70% of the time.
- Agree to regular reviews with the local clinical team.
- GPs should prescribe sensors on an **acute** basis (rather than repeat prescription) until continuation is determined at 6-9 months by the specialist.
- After 6-9 months, a definitive decision regarding ongoing prescribing of FSL should be made by the specialist team. The CCG will fund 26 sensors per year (1 sensor lasts 2 weeks) per patient in line with national guidance.

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This 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.

FreeStyle Libre 2

Freestyle Libre 2 (FSL-2) has additional features such as the audible alarm option which can alert the patient to hyperglycaemia and hypoglycaemia. The lag time between blood glucose levels to interstitial level readings is reduced (2.4minutes) compared to FSL- Version 1 (5-10minutes). This would mean readings are closer to real-time measurements.

Patients who now meet the criteria for flash monitoring will be initiated on the Version 2. Existing patients using FSL-1 meeting the existing criteria will continue using their existing version until routine review with their diabetes healthcare professional is due during which the patient will be switched to using FSL-2. This change can be at either at the request from secondary care or by clinical judgement in primary care setting. For more information for healthcare professionals in Freestyle Libre please click here. The reader for FSL-2 will not be compatible with FSL-1 sensors so to reduce waste existing sensors must be used up (with FSL-1 reader or mobile phone app) before starting FSL-2 reader. Training is available from Abbott for these new features should a patient require. Patients can request new readers from Abbott here. Please note the change in prescription is required first before a reader will be sent.

Frequently Asked Questions (FAQs)

1. **How many sensors will a GP prescribe for a patient?**
   Each sensor lasts for 2 weeks so this is 26 sensors per year. GPs should not prescribe sensors for replacement of faulty sensors.

2. **What should be done if a sensor or reader is faulty?**
   If a sensor (or reader) is faulty the patient should not ask the GP for a prescription replacement but to contact the Abbott Customer Care line, 0800 170 1177 to obtain a replacement sensor (or reader). The patient should contact the care line on the day of the fault and keep any faulty sensors or reader until advised by Abbott.

3. **Will GPs prescribe FreeStyle Libre® glucose testing strips for patients who are assessed to fit the criteria for use of this device?**
   The blood glucose testing strips used in the FreeStyle Libre reader are premium price. There is a need to make the best use of resources to benefit the wider population, and whilst it is anticipated that the use of strips will be reduced to a lower level (e.g. 2-3 boxes per month) by using the FreeStyle Libre flash glucose monitoring system, all patients using this system should be asked to use a suitable formulary blood glucose testing meter and strip. A suitable meter for blood glucose and ketone testing will be provided by the specialist diabetes team free of charge. These meters should be those found on the formulary. Blood glucose test strips should be used when symptoms do not match the readings and/or alarms.

4. **Can drivers use the Flash Glucose Sensors to monitor blood glucose levels prior to driving?**
   The DVLA guidance on glucose testing prior to driving permits the use of interstitial glucose monitoring (Flash Glucose Monitoring) such as using FreeStyle Libre® and Continuous Glucose

Monitoring systems for group 1 drivers only. Click here for further advice as finger prick tests are still required (even for group 1 drivers) under certain circumstances. Group 2 drivers must continue to use finger prick testing for the purposes of driving. RT-CGM and flash glucose monitoring systems are not legally permitted for the purposes of Group 2 driving.

5. **How should the FreeStyle Libre sensor components be disposed of after use?**
   Once the FreeStyle Libre sensor has been placed on the arm, the used applicator (which contains a needle) and the lid can be screwed back together and can be placed in a yellow biohazard bag or sharps box. The used FreeStyle Libre sensor should be placed in a clinical waste sharps box. Sensor packaging can go in general waste.

6. **What about patients who are already self-funding FreeStyle Libre®?**
   Patients who have been buying the FreeStyle Libre® directly from the manufacturer (and wish to continue using the device) should still purchase their sensors via this route until they are reviewed, if appropriate, by the secondary care specialist diabetes team at their next routine clinic appointment. The eligibility criteria still apply if patients wish to obtain supplies with the NHS. It is important to ensure that patients are made aware that future decisions will not be based on what has already been purchased, but on what has been agreed for national NHS funding.

7. **What if the patient wishes to use (or continue using) FreeStyle Libre® but does not meet the national criteria for funding?**
   The patient can purchase FreeStyle Libre® directly from the manufacturer - https://www.freestylelibre.co.uk/libre/ or Tel: 0800 170 1177

8. **Should patients be referred to switch from Freestyle Libre 1 to 2?**
   No - patients should be switched at the next routine review with the diabetes healthcare professional (as above). Patients are advised to continue to use Freestyle Libre 1 sensors until this appointment. All new initiation of FSL will be for Version 2 devices.

9. **Is FreeStyle Libre 1 being discontinued?**
   FreeStyle Libre 1 is still currently available. It is not yet known when or whether this will eventually be discontinued.

Useful References

NHS England. Flash Glucose Monitoring: National Arrangements for Funding of Relevent Diabetes Patients. March 2019.
NICE Medtech Innovation Brief (MIB110). Freestyle Libre for glucose monitoring. July 2017.
Flash Glucose Monitoring - FreeStyle Libre https://freestylediabetes.co.uk/health-care-professionals/freestyle-libre/flash-glucose-monitoring
Abbott Laboratories website https://www.abbott.com/corpnewsroom/strategy-and-strength/freestyle-libre-2-system-accuracy-is-everything.html

Approved by: JPC, KMMOC, Clinical Cabinet
Approved Date: Clinical Cabinet 01/04/2021
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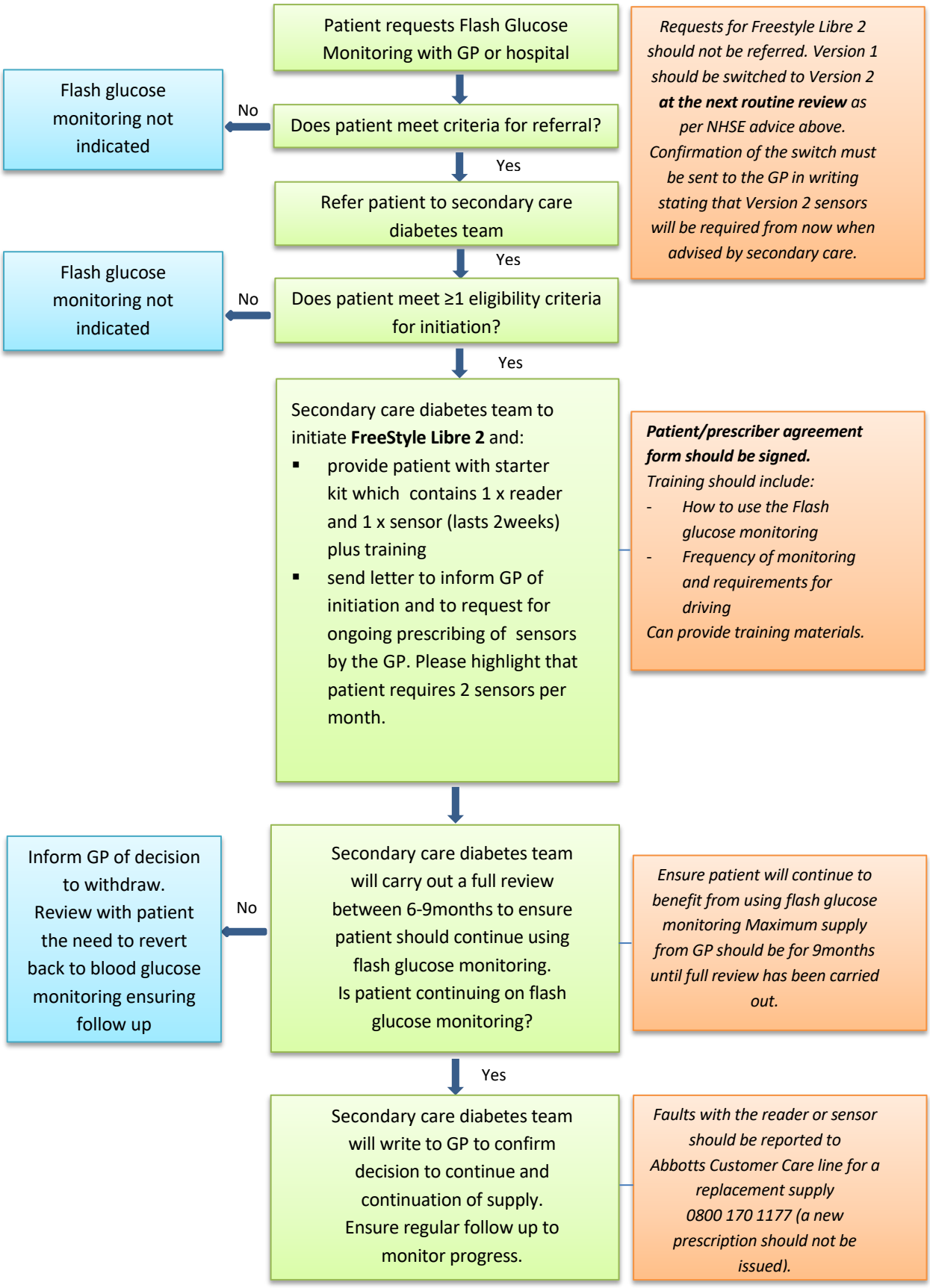
Appendix 1

Flowchart for process of prescribing Flash Glucose Monitoring Systems e.g. FreeStyle Libre.



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Appendix 2

Flash Glucose Monitoring System – FreeStyle Libre
Quick Reference Guide for Primary Care Clinicians

The following is a summary of the treatment pathway for Flash Glucose Monitoring, FreeStyle Libre (FSL) highlighting key points for primary care clinicians.

- **GPs or other primary care clinicians should not initiate FSL.**
  Patients who meet the set criteria for FSL will be initiated by a secondary care diabetes specialist (starter pack contains 1 reader and 1 sensor); subsequent prescriptions will be through the patient's GP.

- **GPs or other primary care clinicians should consider the eligibility criteria prior to making a referral to secondary care diabetes specialist service.**
  Patients not meeting the eligibility criteria should not be referred and should be considered for diabetes review for alternative strategies to manage diabetes. (See the Eligibility Criteria on next page).

- **GPs or other primary care clinicians will be notified in writing when secondary care diabetes specialist has reviewed the patient.**
  From initiation, this will be at 6-9 months with the secondary care diabetes team review. This will indicate whether patients should continue treatment with FSL and therefore for supplies of sensors to continue with GP or to stop if treatment criteria are not being fulfilled.

- **GPs or other primary care clinicians should not make a referral to the diabetes healthcare professional for switching FSL-1 to FSL-2.**
  NHS England advises: To manage workload & product supply, Libre 2 will be offered to patients who meet the eligibility criteria for Flash at their next routine appointment with their diabetes healthcare professional. In the current climate, we respectfully request that patients wait until their next routine appointment with their healthcare team in 2021 to enquire about the FreeStyle Libre 2 system. This change can be at either as above at request from secondary care or by clinical judgement in primary care setting. For more information for healthcare professionals in Freestyle Libre please click here.

- **GPs or other primary care clinicians should prescribe FSL on acute basis until patient is deemed suitable to continue at the 6-9month review with the secondary care diabetes specialist.**
  Once confirmation to continue has been received from the 6-9month review the GP can prescribed on a repeat basis (patients will need 2 sensors per month).

- **GPs or other primary care clinicians should be aware of the incompatibility of FSL-2 readers with FSL-1 sensors**
  The reader for FSL-2 will not be compatible with FSL-1 sensors so to reduce waste existing sensors must be used up (with FSL-1 reader or mobile phone app) before starting FSL-2 reader.

- **GPs or other primary care clinicians will still need to prescribe blood glucose test strips**
  Whilst it is anticipated that the use of strips will be reduced to a lower level (e.g. 2-3 boxes per month) it would still be required for prescribing to patients. Estimated on-going test strip use will be advised by the diabetes specialist service. Blood glucose test strips should be used when symptoms do not match the readings and/or alarms.

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- Pregnant women with Type 1 Diabetes - 12 months in total inclusive of post-delivery period.
- 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.
- 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 FSL with appropriate adjunct support.
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