Flash Glucose Monitoring in South East London (SEL) Guidance

This guidance refers to access to flash glucose monitoring in South East London (SEL) for:

1. People living with type 2 diabetes (T2DM)
2. Children and young people under 18 years living with diabetes
3. Pregnant women who are on insulin therapy but do not have type 1 diabetes (T1DM)

Guidance on access to continuous glucose monitoring (CGM), including access to flash glucose (also known as intermittently scanned CGM) for adults living with type 1 diabetes can be accessed at this webpage. NHS South East London is in the process of reviewing the updated NICE guidelines for access to CGM for groups 1 and 2 above.

1. People living with type 2 diabetes

Eligibility for Flash Glucose (FG) monitoring on NHS prescription for people living with type 2 diabetes

SEL have adopted the recommendations made by NHS England (NHSE) on eligibility for FG monitoring on NHS prescriptions. The specific cohorts of patients are detailed below:

1. (a) People with any form of diabetes on haemodialysis and on insulin treatment, who are clinically indicated as requiring intensive monitoring >8 times daily, as demonstrated on a meter download/review over the past 3 months **OR** (b) with diabetes associated with cystic fibrosis on insulin treatment
2. People with insulin treated Type 2 diabetes who are living with a learning disability and recorded on their GP Learning Disability register.

Patients transferring from other geographical areas should be assessed by the Specialist to ensure they meet one of these criteria and have all the appropriate supporting documentation in place before transfer to new GP.

Clinicians should consider alternative glucose monitoring options for those who fall outside of these cohorts.

2. Children and Young People under 18 years living with diabetes

Eligibility for FG monitoring on NHS prescription for children and young people under 18 years living with diabetes

SEL have adopted the recommendations made by NHS England (NHSE) on eligibility for FG monitoring on NHS prescriptions. The specific cohorts of patients are detailed below:

1. (a) People with Type 1 diabetes mellitus (T1DM) **OR** with any form of diabetes on haemodialysis and on insulin treatment, who in either of these two groups are clinically indicated as requiring intensive monitoring >8 times daily, as demonstrated on a meter download/review over the past 3 months **OR** (b) with diabetes associated with cystic fibrosis on insulin treatment
2. Pregnant women with T1DM - 12 months in total inclusive of post-delivery period
3. People with T1DM unable to routinely self-monitor blood glucose due to disability who require carers to support glucose monitoring and insulin management
4. People with T1DM for whom the specialist diabetes multi-disciplinary team (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 FG monitoring with appropriate adjunct support
5. Previous self-funders of FG monitoring with T1DM 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 FG monitoring had these criteria been in place prior to April 2019 AND has shown improvement in HbA1c since self-funding
6. For T1DM and recurrent severe hypoglycaemia or impaired hypoglycaemia awareness, 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 FG 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.

Patients transferring from other geographical areas should be assessed by the Specialist to ensure they meet one of these criteria and have all the appropriate supporting documentation in place before transfer to new GP.

Clinicians should consider alternative glucose monitoring options for those who fall outside of these cohorts.

 Original approval date: July 2019 **Updated** April 2023 **Review date:** April 2025 sooner if indicated.

3. Pregnant women who are on insulin therapy but do not have type 1 diabetes

Eligibility for Flash Glucose (FG) monitoring on NHS prescription for pregnant women who are on insulin therapy but do not have type 1 diabetes

NHS South East London have approved the following cohort of patients, in line with NICE guidance:

1. For pregnant women who are on insulin therapy but do not have type 1 diabetes (12 months sensors in total inclusive of post-delivery period), if they have:
   a. problematic severe hypoglycaemia (with or without impaired awareness of hypoglycaemia) **OR**
   b. unstable blood glucose levels that are causing concern despite efforts to optimise glycaemic control.

Patients transferring from other geographical areas should be assessed by the Specialist to ensure they meet one of these criteria and have all the appropriate supporting documentation in place before transfer to new GP.

Clinicians should consider alternative glucose monitoring options for those who fall outside of these cohorts.

Considerations for prescribing

FG monitoring may NOT be suitable in some circumstances, even if the patient meets the eligibility criteria. Consider alternatives to FG monitoring for the following patients:

- Caution should be noted for those with hypoglycaemia unawareness and/or frequent (more than 2 episodes a week) asymptomatic hypoglycaemia that is causing problems with daily activities. The Freestyle Libre 2® device does have limited alert functionality (see next page) however in this specific setting other evidence based options (real-time CGM) may be more suitable for individual patients
- Those with an allergy to medical grade adhesive.
- Children and young people under 18 years on continuous subcutaneous insulin infusion (CSII) who need to test their blood glucose frequently to make insulin dosing decisions, including with pump algorithms. A reasonable number of self-monitoring of blood glucose (SMBG) strips will be required for this as many require blood glucose measurements. Some pump devices (e.g. Medtronic 640G) can use glucose levels from interstitial fluid for these calculations but blood glucose is deemed to be more appropriate. If interstitial glucose levels are to be measured and used with pumps where the algorithm supports this, ideally this should be from a CGM device.
- Patients (or carers, where appropriate) who have not had appropriate basic diabetes education to date, covering at the very least: principles of insulin dose adjustment, appropriate management of hypoglycaemia and hyperglycaemia, and general self-management. These must be completed first, including follow-up, before considering introducing FG.
- Those not under the care of a specialist team with skills to support the initiation of FG

NB the use of FG must be associated with sufficient training and engagement in order to ensure that its use is safe and effective for ongoing measurement of glucose levels.

Expected outcomes

In order to gain maximum benefit from the device, sensors should be worn >70% of the time and scanned no less than 8 times per day. At the 6-9 month review, continuation of therapy is only indicated if there is evidence that on-going use of flash glucose monitoring is demonstrably improving an individual's diabetes self management e.g. :

a) HbA1c or time in range: achievement of a clinically significant reduction in HbA1c of 0.4% (4mmol/mol)
b) Reductions in episodes of diabetic ketoacidosis (DKA) or reductions in hypoglycaemia: any reduction
c) Improvement in psychosocial wellbeing: achievement of a clinically significant reduction in a validated psychosocial wellbeing score used by the specialist diabetes team
d) Significant reduction in test strip use: safe and appropriate reduction of 8/day for adults or 7/day for children

If the agreed benefits and outcomes have not been achieved by 6-9 months, the initiating team and patient should have a discussion as to why this may not be. If it is agreed that it is unlikely any further improvements will be seen, then the use of FG should be discontinued.

Does FG monitoring replace fingerprick blood glucose testing?

FG measures glucose levels in the interstitial fluid, it is not a complete substitute for blood glucose (BG) testing. Therefore, SMBG measurements are required in certain circumstances, including:

a) to meet driving and vehicle licensing agency (DVLA) requirements
b) when scanned glucose results do not correspond with the user's symptoms e.g when the scan result indicates a low glucose reading however the user's symptoms do not match
c) to use bolus calculators
d) during times of rapidly changing glucose levels when interstitial fluid glucose levels may not accurately reflect BG levels

The average daily number of test strips required for the individual should be discussed and sufficient test strips should be provided in addition to FG sensors. This will be documented on the '*Transfer of Prescribing Request and Patient-Prescriber Agreement - Flash Glucose'* form.

The Freestyle Libre 2® device has the option to use the handset as a SMBG and ketone meter, in conjunction with FreeStyle Optium® blood glucose and ketone strips. It is not essential to use this functionality (and these strips) and patients can continue to use their current SMBG meter and ketone meter alongside the Freestyle Libre 2® device. **It is important to ensure that patients have enough testing strips for SMBG as per their requirements. However, the brand chosen should reflect local formularies, the functionality required by the individual, patient choice and cost effectiveness.**

This guidance has been adapted from the Implementation of Freestyle Libre ® prescribing guidance across the NHS in London document with kind permission from NHS Clinical Networks and NHS London Procurement Partnership and Dartford and Gravesham NHS Trust

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Specialist initiaton (via next routine appointment)

- Patient meets NHSE criteria for FG and decision made to initiate
- Patient and clinician to read, complete then clinician to sign *'Transfer of Prescribing Request and Patient-Prescriber Agreement - Flash Glucose'* **Not to be sent to GP at this stage (see 1 month virtual review)**
- Patients who meet eligibility criteria, to attend FG education session
- Specialist team to send *'FG initiation letter - notification'* to GP highlighting FG has been started once patient attended education session (or add content into clinic letter)
- Patient supplied with FG starter kit (1 reader and 1 sensor) and further 2 sensors to last 6 weeks (prescription supplied by specialist team), at the education session.
- Specialist team to complete data collection as required

1 month virtual review (specialist team)

- Specialist team to review use/issues and ensure patients are aware of NHSE criteria for use and are on track for their 6-9 month review
- Once the patient has attended the 1 month review and meet the continuation criteria, specialist team to send *'Transfer of Prescribing Request and Patient-Prescriber Agreement - Flash Glucose'* to GP to request prescribing of FG sensors until specialist review in 6-9 months time
- If patient is not continuing with FG monitoring, specialist team to notify GP practice that FG has not been continued

GP Prescribing

- GP to issue repeat prescriptions for FG **ONLY** on receipt of completed *'Transfer of Prescribing Request and Patient-Prescriber Agreement - Flash Glucose'* from diabetes clinic. GP to take on prescribing 6 weeks after initiation
- Approximately 2 sensors/month, approximately 27 sensors/annum on the NHS
- New requests or current self funders should be assessed at their next routine specialist diabetes team appointment
- Additional outpatient referrals should not be made purely for the purpose of changing to NHS funding for sensors
- Patients must arrange replacements for faulty sensors and readers via Abbott (see FAQ document)

6-9 monthly reviews (specialist team)

- At first 6-9 month review - Specialist team to review continuation of FG against NHSE continuation criteria. Where continuation criteria have not been met, FG sensors should be stopped. Specialist team to complete and send *'Flash Glucose Monitoring 6-9 month Review'* letter to GP highlighting whether outcomes have been met and whether the GP should continue/discontinue FG NHS prescriptions
- Specialist team to complete data collection as required
- Specialist team to review and document clinical benefit at least annually thereafter (as per NHSE continuation critera) and inform GP about review outcome in usual clinic letter
- Where patient does not attend appointments, specialist team to liaise with GP practice regarding ongoing prescribing of FG sensors

Please note, this process is for children and young people living with diabetes and people living with type 2 diabetes who meet the eligibility criteria on page 1. This process is not required for adults with type 1 diabetes – please see SEL guidance on access to CGM for adults living with type 1 diabetes at this webpage

South East London Integrated Medicines Optimisation Committee (SEL IMOC). A partnership between NHS organisations in South East London Integrated Care System: NHS South East London (covering the boroughs of Bexley/Bromley/Greenwich/ Lambeth/Lewisham and Southwark) and GSTFT/KCH /SLaM/ Oxleas NHS Foundation Trusts and Lewisham & Greenwich NHS Trust

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