South East London Integrated Medicines Optimisation Committee
Flash Glucose Monitoring systems
Position Statement

Reference:	**PS-018**
Intervention:	**Flash Glucose Monitoring systems for use in children and young people living with diabetes and in adults living with type 2 diabetes.** **For information regarding use of continuous glucose monitoring (including flash glucose monitoring systems) in adults with type 1 diabetes, please see guidance here**
Date of Decision:	**June 2019. Updated March 2021, updated December 2021 to incorporate use in pregnant women who are on insulin but don't have Type 1 diabetes (follows a formulary application). Updated April 2023**
Date of Issue:	**July 2019. Re-issued March 2021 to incorporate Freestyle Libre 2 and guidance on use in people with learning disabilities. Re-issued Dec 2022. Re-issued April 2023.**
Recommendation:	**AMBER 3** **FreeStyle Libre ® recommended for prescribing for the patient groups listed below in South East London from July 2019 and FreeStyle Libre® 2 recommended for prescribing for the patient groups listed below in South East London from March/April 2021** **Assessment of NHS eligibility for flash glucose monitoring systems will be completed by the diabetes specialist teams through existing routine out-patient appointments. This includes people currently self-funding their own Flash Glucose Monitoring system.** **Initiation and prescribing for eligible patients will be the responsibility of specialist services for first 6 weeks before transfer of prescribing to primary care if criteria are met. People who are currently self-funding their own Flash Glucose Monitoring system may be transferred to primary care earlier than 6 weeks if criteria are met.**
Further Information:	In line with NHS England, the seven distinct groups of patients for whom the use of FreeStyle Libre® and FreeStyle Libre® 2 is accepted in SEL are as follows: 1. 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 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 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. 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. 8. 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: 1. problematic severe hypoglycaemia (with or without impaired awareness of hypoglycaemia) **OR**

	2. unstable blood glucose levels that are causing concern despite efforts to optimise glycaemic control.

Further Information (continued):	**<u>Other requirements:</u>** 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 sensors should be worn >70% of the time 3. Agree to regular reviews with the local clinical team at least annually. Previous attendance, or due consideration given to future attendance, at a Type 1 diabetes structured education programme (DAFNE or equivalent if available locally) After a period of 6-9 months, the specialist diabetes team will review the use of the flash glucose monitoring system with the patient. Flash glucose monitoring will only be continued 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 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 The specialist diabetes team will also review the use of flash glucose monitoring systems at every clinic appointment to make sure it is still suitable. The South East London Integrated Medicines Optimisation Committee (IMOC) has considered the following guidance in this recommendation and this recommendation is in agreement with the key points and distinct groups/treatment areas: • NHS England Flash Glucose Monitoring: National Arrangements for Funding of Relevant Diabetes Patients: National-arrangements-for-funding-of-relevant-diabetes-patients-June-2020-Updated-final.pdf (england.nhs.uk) (updated November 2020) • NHS England London Diabetes Clinical Network and NHS London Procurement Partnership Guidance for the implementation of flash glucose monitoring prescribing in London: http://www.londonscn.nhs.uk/publication/guidance-for-the- implementation-of-flash-glucose-monitoring-prescribing-in-london/
Supporting Resources	The following resources have been developed by the diabetes sub-group of the SEL IMOC to support implementation of flash glucose monitoring (FreeStyle Libre® and FreeStyle Libre® 2 across South East London in a consistent way and can be accessed from the SEL IMOC webpage here: - Pathway and guidance for use of flash glucose monitoring - Recommended training competencies and resources - FreeStyle Libre® and FreeStyle Libre® 2 Primary care information sheets - Additional information for community pharmacies about FreeStyle Libre® and FreeStyle Libre® 2 - Safe disposal guidance - Flash glucose initiation letter - Transfer of prescribing and patient-prescribing agreement form - Flash glucose 6-9 month review - Patient FAQ document - Primary care letter informing of switch from FreeStyle Libre® to FreeStyle Libre® 2

Background	i. Flash glucose monitoring systems are devices for the self-monitoring of glucose levels. Unlike traditional finger-prick devices (that measure the glucose level in the blood), they measure the glucose level in the interstitial fluid, via a sensor that sits just under the skin. ii. It can provide a near-continuous record, which is produced by the patient scanning the sensor with their reader-device, as and when required. iii. Flash glucose monitoring is not a substitute for blood glucose testing and finger-prick blood glucose measurements are required in certain circumstances e.g. in line with Driver and Vehicle Licensing Agency, DVLA guidance, if (impending) hypoglycaemia or when interstitial fluid glucose levels may not accurately reflect blood glucose levels as outlined in the SEL Pathway iv. Additional education and training is necessary for any healthcare professionals or patients who wish to use this system. v. FreeStyle Libre® and FreeStyle Libre® 2 are currently the only flash glucose monitoring devices available in the UK and have been listed in the Drug Tariff from 1st November 2017 and November 2020 respectively. NICE have issued a 'Medtech Innovation Briefing' for FreeStyle Libre® which summarised the costs, evidence base and perceived benefits, but concludes that the resource impact is uncertain. It does not include recommendations on whether it should be prescribed. At time of writing, NICE guidelines use of glucose monitoring in people with Type 1 diabetes, Type 2 diabetes and in Diabetes (type 1 and type 2) in children and young people are under development.
Cost Impact for agreed patient group	NHS England have estimated that the criteria represent up to 20% of England's type 1 diabetes population. Local intelligence estimates that the criteria would cover more than 20% of the Type 1 diabetes population. **December 2021 - Pregnant women on insulin who do not have Type 1 diabetes:** The cost of each FreeStyle® libre sensor is £35, with each sensor lasting 2 weeks. It is estimated that across the specialist services in South East London, 118 patients per annum would be appropriate for treatment, of whom 90% would be from South East London. If 10% of patients stop treatment at 3 months owing to being unable to use it, or owing to stabilisation of blood glucose levels, and if the average treatment course was 12 months (as per NHS England guidance for use in patients with type 1 diabetes), this equates to approximately £85K costs per annum for SE London (or ~£4,500 per 100,000 population).
Usage Monitoring & Impact Assessment	**Acute Trusts** • Ensure this advice is cascaded to relevant teams within the organisation and that use of flash glucose monitoring systems are implemented in line with local guidance (including training and transfer of prescribing). • Participation in flash glucose monitoring systems audit • Provide quarterly monitoring and audit data to the IMOC
	Borough Medicines Optimisation teams: • To ensure local primary care prescribers and commissioned diabetes services are aware of this recommendation. • Monitor epact 2 data at least quarterly • Monitor exception reports from GPs if inappropriate prescribing requests are made in primary care.
Key references:	1. NHS England Flash Glucose Monitoring: National Arrangements for Funding of Relevant Diabetes Patients: (Updated November 2020) 2. NHS England London Diabetes Clinical Network and NHS London Procurement Partnership Guidance for the implementation of flash glucose monitoring prescribing in London: http://www.londonscn.nhs.uk/publication/guidance-for-the-implementation-of-flash-glucose-monitoring- prescribing-in-london/ 3. National Institute for Health and Care Excellence (NICE). MIB110: FreeStyle Libre® forglucose monitoring. (2017). Available here, last accessed:08.03.2021

NOTES:

a) IMOC recommendations, position statements and minutes are available publicly via the IMOC webpages.

b) This SEL IMOC position statement has been made on the cost effectiveness, patient outcome and safety data available at the time. The position statement will be subject to review if new data becomes available, costs are higher than expected or new NICE guidelines or technology appraisals are issued.

c) **Not to be used for commercial or marketing purposes. Strictly for use within the NHS**.