

**South East London Area Prescribing Committee
FreeStyle Libre® Flash Glucose Monitoring system –
INTERIM Position Statement**

Reference:	PS-004 (updated July 2018)
Intervention:	FreeStyle Libre® Flash Glucose Monitoring system
Date of Decision:	Original decision: October 2017, last updated July 2018
Date of Issue:	July 2018
INTERIM Recommendation:	Not recommended for prescribing in South East London until mechanisms have been put in place to support delivery of the local implementation plan
Further Information:	<ul style="list-style-type: none"> • On the 1st of November, a national position statement was issued by the NHS England Regional Medicines Optimisation Committee (RMOC): https://www.sps.nhs.uk/articles/regional-medicines-optimisation-committee-freestyle-libre-position-statement/ • The NHS England London Diabetes Clinical Network and NHS London Procurement Partnership recently released implementation guidance for the prescribing of FreeStyle Libre® in London. • The South East London Area Prescribing Committee considered this implementation guidance and is broadly in agreement with the key points and distinct groups/treatment areas. However the committee identified several operational issues for further local discussion and agreement before prescribing can safely and effectively take place. Mechanisms are currently being put in place to support delivery of a local implementation plan. It is not possible to place an exact date for completion of the local implementation plan however, it is anticipated that eligible patients will be able to access FreeStyle Libre® on the NHS in South East London in Autumn 2018. <p>The three distinct groups/treatment areas which have been agreed are as follows:</p> <ol style="list-style-type: none"> 1. Recommended implementation of FreeStyle Libre® prescribing for patients with Type 1 diabetes on Multiple Daily Injections or insulin pump therapy who test frequently. 2. Recommended implementation of FreeStyle Libre® prescribing for patients with Type 1 diabetes with HbA1c >8.5% (69.4mmol/mol) or disabling hypoglycaemia who would be eligible for insulin pump therapy as per NICE Technology Appraisal Guidance 151 (plus additional notes on those who can be considered for continuous glucose monitoring as per NICE Guideline 17 and NICE Guideline 18). 3. Recommended implementation of FreeStyle Libre® prescribing for patients with Type 1 diabetes on Multiple Daily Injections or insulin pump therapy where conventional monitoring is not possible with Self Monitoring of Blood Glucose tests.

Background	<ol style="list-style-type: none"> i. The FreeStyle Libre® flash glucose monitoring system is a device for the self-monitoring of glucose levels. Unlike traditional finger-prick devices (that measure the glucose level in the blood), FreeStyle Libre® measures 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. It will not provide warnings or alarms about low or high glucose levels and finger-prick blood glucose measurements are required in certain circumstances e.g. before and during driving (as required by the Driver and Vehicle Licensing Agency, DVLA), if (impending) hypoglycaemia or when interstitial fluid glucose levels may not accurately reflect blood glucose levels. iv. Additional education and training is necessary for any healthcare professionals or patients who wish to use this system. v. FreeStyle Libre® has been listed in the Drug Tariff from 1st November 2017. vi. NICE has not issued guidance on the use of FreeStyle Libre®; it issued a 'Medtech innovation briefing' 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.
Cost Impact for agreed patient	<ul style="list-style-type: none"> • The cost impact of this intervention is being evaluated/assessed and will be included once completed.
Usage Monitoring & Impact Assessment	<p>Acute Trusts</p> <ul style="list-style-type: none"> • Ensure this interim advice is cascaded to relevant teams within the organisation and monitor non-formulary requests. • Provide data to the Area Prescribing Committee upon request. <p>Clinical Commissioning Groups (CCG)</p> <ul style="list-style-type: none"> • To ensure local primary care prescribers and commissioned community diabetes services are aware of this interim recommendation. • Monitor impact data • Monitor exception reports from GPs if prescribing requests are made in primary care.
Key references:	<ol style="list-style-type: none"> 1. NHS London Procurement Partnership, Medicines Optimisation Workstream - Responsible Diabetes Prescribing Group: Current advice on the prescribing of FreeStyle Libre® in London. October 2017 2. National Institute for Health and Care Excellence (NICE). MIB110: FreeStyle Libre for glucose monitoring. (2017). Available at: https://www.nice.org.uk/advice/mib110/chapter/Summary. (Accessed: 16.10.17) 3. North Central London Joint Formulary Committee - Interim Position Statement for GPs & Patient FAQ (September 2017): available here. 4. Regional Medicines Optimisation Committee FreeStyle Libre Position Statement : https://www.sps.nhs.uk/articles/regional-medicines-optimisation-committee-freestyle-libre-position-statement/

NOTES:

- a) Area Prescribing Committee recommendations, position statements and minutes are available publicly via the [APC webpages](#).
- b) This is an INTERIM Area Prescribing Committee position statement.
- c) **Not to be used for commercial or marketing purposes. Strictly for use within the NHS.**

Approval date: July 2018

Review date: To be reviewed when mechanisms have been put in place to support delivery of the South East London implementation plan

FreeStyle Libre Flash Glucose Monitoring System
Frequently Asked Questions for Healthcare professionals
(To be read in conjunction with the South East London Area Prescribing Committee's INTERIM position statement)
Updated July 2018

a. What changed on 1st November 2017?

- From 1st November 2017, the FreeStyle Libre® was listed in the Drug Tariff under section 9A (Detection Sensor, interstitial fluid for glucose), which allows it to be prescribed on NHS prescriptions in the community.
- However, it is important to note that the Drug Tariff is not a list of recommended products and a review process is still required at a national and/or local level to decide whether it is included in the local formulary.
- NHS organisations and prescribers are not obligated to supply every item listed in the Drug Tariff and can decide to restrict prescribing if an evaluation of the evidence finds that the device is not cost-effective or unsuitable for local use.
- The NHS England London Diabetes Clinical Network and NHS London Procurement Partnership (LPP) recently released implementation guidance for the prescribing of FreeStyle Libre® in London.
- A more detailed local implementation plan has been agreed. Mechanisms are currently being put in place to support delivery of this plan which focuses on areas that need to be addressed locally for example staff and patient training to enable safe and effective prescribing. Therefore, we are not expecting clinicians in South East London to prescribe FreeStyle Libre® sensors and would recommend they do not prescribe until mechanisms have been put in place to support delivery of the implementation plan.

b. Why has FreeStyle Libre® been evaluated once for all of London?

- Most medicines and devices used in the NHS are subject to review by a local formulary or equivalent committee. This process ensures that local decisions are robust and are informed by a review of evidence to demonstrate the clinical benefits and cost-effectiveness of products, which will usually inform their place in local treatment pathways.
- On the 1st November 2017, the Regional Medicines Optimisation Committee (RMOC) issued a national position statement for the use of flash glucose monitoring in 5 groups of patients but in the context of clinical priorities and configuration of services within the London region, London RMOC members felt that more detailed guidance is essential for London.
- To address this, the London Diabetes Clinical Network, working in collaboration with the NHS LPP, has developed guidance to support implementation in London.

c. Who was involved in the collaborative work to review FreeStyle Libre® and develop London-wide prescribing recommendations for it?

- A number of regional clinical groups across London worked together with local commissioners to independently review the clinical and cost-effectiveness data available and produce recommendations on the prescribing of FreeStyle Libre®. These groups - listed below - have a variety of clinician and patient representatives and represent both adult and paediatric people with diabetes:
 - London Diabetes Clinical Network
 - London Type 1 Diabetes Network
 - Children and Young People's South East Coast & London Diabetes Network
 - Healthy London Partnership

d. What was the result of this review?

- London-wide guidance has been developed that provides recommendations on the appropriate place in therapy for Freestyle Libre® and information regarding ongoing monitoring and review. The guidance includes documentation to support the transfer of care from the diabetes specialist team to primary care.

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e. Is this a type of Continuous Glucose Monitoring (CGM)?

- Flash glucose monitoring should not be confused with Continuous Glucose Monitoring (CGM) and is not a suitable alternative for patients who are eligible for this technology in accordance with NICE guidance.
- Therefore, the outcome of this review should not delay the referral of any patients eligible for CGM; any patient who requires CGM should be reviewed by a consultant-led diabetic specialist team.

f. What about people 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 the South East London implementation plan has been fully completed when further information will be provided.
- It is possible that future recommendations may not enable all privately paying patients to receive FreeStyle Libre® on an NHS prescription. Therefore, 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 local NHS funding.

g. What about people who have previously received their device and sensors from hospital?

- The supply route for patients who may have been receiving FreeStyle Libre® via the hospital should not change from 1st November 2017.
- It is not guaranteed that FreeStyle Libre® will automatically be prescribed in primary care if it was previously received from a hospital; as with other specialist items, prescribing in primary care should be as per local formulary agreements and it is possible that prescribing may need to stay in hospital, under the care of the specialist team.

h. What are the timescales for the completion of the South East London Implementation plan?

It is not possible to place an exact date for completion of the local implementation plan however, it is anticipated that eligible patients will be able to access FreeStyle Libre® on the NHS in South East London in Autumn 2018.

i. Who can be contacted for updates on these recommendations?

- During the interim period, individual CCGs in SEL will need to locally manage queries relating to FreeStyle Libre® arising in their boroughs.