

**South East London Area Prescribing Committee  
FreeStyle Libre® Flash Glucose Monitoring system –  
INTERIM Position Statement, October 2017**

<b>Reference:</b>	<b>PS-004</b>
<b>Intervention:</b>	<b>FreeStyle Libre® Flash Glucose Monitoring system</b>
<b>Date of Decision:</b>	<b>October 2017</b>
<b>Date of Issue:</b>	<b>October 2017</b>
<b>INTERIM Recommendation:</b>	<b>Not recommended for prescribing in South East London until either London-wide or National recommendations for prescribing the sensors have been established.</b>
<b>Further Information:</b>	<ul style="list-style-type: none"> <li>• This interim position statement is based on advice developed through the NHS London Procurement Partnership (LPP) Responsible Diabetes Prescribing Group. The South East London Area Prescribing Committee (SEL APC) has considered this advice and supports the NHS LPP recommendations.</li> <li>• FreeStyle Libre® will be added to the national Drug Tariff from 1st November 2017. It is important to note that the Drug Tariff is not a list of recommended products and NHS organisations and prescribers are not obligated to supply every item listed within it. There are currently no national recommendations for the prescribing of Libre®.</li> <li>• A number of NHS clinical groups will be collaborating with commissioners to produce recommendations for the prescribing of FreeStyle Libre® in London; this will assist NHS organisations in the evaluation process and avoid variation in practice.</li> <li>• The recommendations from this group will not be published before 1<sup>st</sup> November 2017, but regular updates will be circulated by the NHS LPP Responsible Diabetes Prescribing Group.</li> <li>• Prescribers in primary care <b>should not prescribe</b> Freestyle Libre® sensors on an NHS prescription until the Freestyle Libre® device has been evaluated and approved for use through the SEL APC.</li> <li>• This interim position statement will be reviewed and updated when the approach to prescribing has been agreed at a London-wide or national level and locally approved by the SEL APC.</li> </ul> <p><b>Note:</b> The NHS LPP has agreed this advice with senior members from the NHS England London diabetes clinical networks and the Children and Young People's South East Coast &amp; London Diabetes Network, as well as stakeholders within the LPP Responsible Diabetes Prescribing Group.</p>
<b>Background</b>	<ol style="list-style-type: none"> <li>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), Libre® measures the glucose level in the interstitial fluid, via a sensor that sits just under the skin.</li> <li>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.</li> <li>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 DVLA), if (impending) hypoglycaemia or when interstitial fluid glucose levels may not accurately reflect blood glucose levels.</li> <li>iv. Additional education and training is necessary for any healthcare professionals or patients who wish to use this system.</li> <li>v. FreeStyle Libre® will be listed in the Drug Tariff from 1st November 2017.</li> <li>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.</li> <li>vii. NHS networks in London are working together to identify the patient groups most likely to benefit from FreeStyle Libre®.</li> </ol>

<b>Cost Impact for agreed patient group</b>	<ul style="list-style-type: none"> <li>The cost impact of this intervention is uncertain, further detail will be provided once prescribing recommendations have been established for London.</li> </ul>
<b>Usage Monitoring &amp; Impact Assessment</b>	<b>Acute Trusts</b> <ul style="list-style-type: none"> <li>Ensure this interim advice is cascaded to relevant teams within the organisation and monitor non-formulary requests.</li> <li>Provide data to the APC upon request.</li> </ul>
	<b>CCGs</b> <ul style="list-style-type: none"> <li>To ensure local primary care prescribers and commissioned community diabetes services are aware of this interim recommendation.</li> <li>Monitor impact data</li> <li>Monitor exception reports from GPs if prescribing requests are made in primary care.</li> </ul>
<b>Key references:</b>	<ol style="list-style-type: none"> <li>NHS London Procurement Partnership, Medicines Optimisation Workstream - Responsible Diabetes Prescribing Group: Current advice on the prescribing of FreeStyle Libre® in London. October 2017</li> <li>National Institute for Health and Care Excellence (NICE). MIB110: FreeStyle Libre for glucose monitoring. (2017). Available at: <a href="https://www.nice.org.uk/advice/mib110/chapter/Summary">https://www.nice.org.uk/advice/mib110/chapter/Summary</a>. (Accessed: 16.10.17)</li> <li>North Central London Joint Formulary Committee - Interim Position Statement for GPs &amp; Patient FAQ (September 2017): available <a href="#">here</a>.</li> </ol>

**NOTES:**

- Area Prescribing Committee recommendations, position statements and minutes are available publicly on member CCG websites.
- This is an INTERIM Area Prescribing Committee position statement that is based on advice from the NHS London Procurement Partnership. The LPP will be developing prescribing recommendations based on cost effectiveness, patient outcome and safety data. This interim position statement will be subject to review once the NHS LPP establishes prescribing recommendations for FreeStyle® Libre.
- Not to be used for commercial or marketing purposes. Strictly for use within the NHS.**

**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)**  
**October 2017**

**a. What changes on 1st November 2017?**

- From 1st November 2017, the FreeStyle Libre® will be 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.
- Therefore, we are not expecting clinicians in primary care to start prescribing Libre® sensors from 1<sup>st</sup> November 2017 and would recommend they do not until we have the guidance from the collaborative London-wide group.

**b. Why is FreeStyle Libre being 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.
- However, this can result in slight differences in access across areas. An evaluation and recommendations for London should help ensure equal access.
- In addition, this device has a limited amount of clinical trial data, which can make it more difficult to review.

**c. Who is 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 have agreed to work 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 will be the result of this review?**

- If FreeStyle Libre® is considered to be clinically and cost-effective, it is likely that recommendations will include advice on its appropriate place in therapy and suggestions for ongoing monitoring and reviews.
- These recommendations will be issued to Clinical Commissioning Groups (CCGs) in London, who will be able to use this information to conduct their own local reviews. They will need to consider Libre® against other items competing for NHS resources in order to make a decision on the level of local funding available.

**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.

**Approval date:** October 2017

**Review date:** To be reviewed when London-wide or national recommendations have been developed

**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 it has been reviewed at a local level.
- 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 1<sup>st</sup> 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 London review?**

- It is not possible to place an exact completion date on these discussions, but clinicians, patient representatives and commissioners will be meeting regularly over the coming months and updates will be circulated via the NHS London Procurement Partnership (LPP) Responsible Diabetes Prescribing Group.
- Subsequent consideration of recommendations will be determined by usual timescales of local governance processes, which may vary between organisations.

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

- The NHS LPP Responsible Diabetes Prescribing Group will circulate updates via membership communication channels and Chief Pharmacist and CCG lead networks. It is then the responsibility of individual CCGs to share these with their providers and patients.
- During the interim period, individual CCGs in SEL will need to locally manage queries relating to FreeStyle Libre® arising in their boroughs.