North East Hampshire and Farnham
Clinical Commissioning Group

# Medicines Optimisation Interim Position Statement - update

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| Position Statement | **Update: Recommendations for prescribing of 'Flash' glucose monitors (such as Freestyle Libre®) in diabetes in patients 4 years and above** |
| Position Statement number | 007 (2017) update |
| Approved by Clinical Executive: | February 2018 |
| Date of issue: | February 2018 |
| Date of review: | An updated position statement will be issued once there has been final agreement with secondary care specialists. |

At the CCG Clinical executive meeting on February 7th 2018 it was agreed that the recommendations for prescribing of the Flash Glucose Monitoring System (FGS) FreeStyle Libre® will be in line with the local Southampton, Hampshire, Isle of Wight, Portsmouth (SHIP8) Priorities Committee[1] and the Regional Medicines Optimisation Committee North (RMOC)[2].

## Interim Recommendations (adapted from the SHIP8 Priorities Committee)

Freestyle Libre® may be **recommended** in patients with Type 1 diabetes 4 years and above or with gestational diabetes and who fulfil **one or more** of the criteria below:

- Patients who are clinically required to undertake intensive monitoring with 8 or more finger prick blood tests daily;
- Those who meet the current NICE criteria for insulin pump therapy (HbA1c >8.5% 69.4mmol/mol) or disabling hypoglycaemia as described in NICE TA151 where a successful trial of flash glucose monitoring may avoid the need for pump therapy;
- Those who have recently developed impaired awareness of hypoglycaemia, when it may be used as an initial tool in its management with a review at 6 months
- Frequent (>2 per year) hospital admissions with diabetic ketoacidosis or hypoglycaemia where other management plans have failed;
- Those requiring third parties to carry out monitoring or where conventional blood testing is not possible.

FreeStyle Libre® should only be initiated by a secondary care consultant- led NHS service.

Primary Care Prescribers should NOT be expected to initiate prescribing.

The patient should have previously been through an advanced insulin self-management education course such as DAFNE (Dose Adjustment For Normal Eating)[3] or other locally accredited education programme. The patient should be actively engaged in enrolling themselves into the management system and would be expected to go through a further course of education on the use and interpretation of the readings the management system delivers.

If no improvement is demonstrated in one or more of the impact areas below over a 6 month trial period, then the use of Flash glucose monitoring should be reviewed with alternative methods of monitoring considered.

- Reductions in severe/non-severe hypoglycaemia
- Reversal of impaired awareness of hypoglycaemia
- Episodes of diabetic ketoacidosis
- Admissions to hospital
- Reduction in HbA1c by more than 0.5% where appropriate
- Blood Glucose Testing strip usage reduced
- Quality of Life changes using validated rating scales
- Commitment to regular scans and their use in self-management.

In addition:

- It is recommended that prescribing and monitoring of the device will remain with specialist prescribers for at least the first 6 months. Prescribing may be transferred to the GP after 6 months if it has been assessed appropriate for the patient to continue.
  The use of patient agreement forms and specialists taking part in a national audit will be encouraged.

- Patients fulfilling the criteria for prescribing are likely to be seen by a specialist at their routine appointment.

- Patients who have obtained FGS through clinical trials or private treatment, or who have been self-funding, must demonstrate that they satisfied the prescribing criteria when they commenced the use of FGS as well as meeting the continuation criteria, to receive FGS on NHS prescription.

- In order to provide consistency for patients and prescribers across the local area (Frimley Health and Care System) discussions will be taking place in the near future with neighbouring Clinical Commissioning Groups and secondary care (Frimley Health NHS Foundation Trust) specialists to agree the process for prescribing. An updated position statement will then be issued.

## Background Information on FreeStyle Libre®

- FreeStyle Libre® is an innovative device that measures interstitial glucose levels from a disposable sensor applied to the skin as an alternative to routine finger-prick blood glucose testing and can produce a near continuous record of measurements which can be accessed on demand (known as Flash Glucose Monitoring (FGS)). The sensor has to be replaced every 14 days. The intended place in therapy is as an alternative to routine blood glucose monitoring in people with type 1 and 2 diabetes who use insulin injections.

- There is currently limited evidence to support the use of FreeStyle Libre®. Its accuracy is inadequately studied, especially in poorly controlled patients and younger patients. The device may offer some advantages in terms of patient acceptability and quality of life but good quality clinical trial data to support long-term clinical effectiveness, an improvement in patient oriented outcomes and cost-effectiveness is lacking.

- A finger-prick test using a blood glucose meter is still required during times of rapidly changing glucose levels when interstitial fluid glucose levels may not accurately reflect blood glucose levels (i.e. acute illness such as Influenza, diarrhoea and vomiting), if hypoglycaemia or impending hypoglycaemia is reported, or the symptoms do not match the

system readings. FreeStyle Libre® users will still need to perform finger-prick blood tests prior to and during driving to meet current DVLA requirements.

## References


1. SHIP8 Clinical Commissioning Groups Priorities Committee: Policy Recommendation: 'Flash' glucose monitoring in diabetes – January 2018

2. (NHS England) Regional Medicines Optimisation Committee (RMOC (North)) Flash Glucose Monitoring Systems position statement November 2017 https://www.sps.nhs.uk/articles/regional-medicines-optimisation-committee-freestyle-libre-position-statement/

3. Department of Health, Diabetes UK (2005) Structured patient education in diabetes: Report from the Patient Education Working Group. DH, London. Available at: http://bit.ly/d2U9DW