

## Use of FreeStyle Libre<sup>®</sup> flash glucose monitoring system in NHS Grampian - Position Statement September 2018

The FreeStyle Libre<sup>®</sup> flash glucose monitoring system is a sensor based, factory-calibrated system that measures interstitial fluid glucose levels, rather than blood glucose levels, in people (aged 4 years and over) with Diabetes Mellitus.

Whilst the glucose measurement of FreeStyle Libre<sup>®</sup> is no better than the blood glucose testing systems currently used it allows glucose levels to be measured without finger pricking and provides information regarding the trend in glucose levels that blood glucose testing does not. Evidence to date indicates that this has the potential to encourage patients and their carers to measure glucose levels more frequently and use that information to manage their diabetes better.

The Scottish Health Technologies Group (SHTG) published its [advice](#) regarding the use of FreeStyle Libre<sup>®</sup> in Scotland on 13/07/2018. Having reviewed this advice the Grampian Diabetes Managed Clinical Network Devices Subgroup have developed an implementation plan for the use of FreeStyle Libre<sup>®</sup> in Grampian to ensure that those with the greatest clinical need for this device benefit first. That focussed approach involves providing FreeStyle Libre<sup>®</sup> to eligible adults with Type 1 diabetes and all children with Type 1 diabetes for whom the product is clinically appropriate.

Due to the potential for benefit for FreeStyle Libre<sup>®</sup> being through encouraging people to more frequently test and better manage their diabetes there is a requirement for all people who will use FreeStyle Libre<sup>®</sup> to undertake / have undertaken training in both how to manage their diabetes and how to make the best use of their device. The adult diabetes service is planning to provide around 120 training places per month which will be enough for all of the eligible adult patients, known to the service, to have access to FreeStyle Libre<sup>®</sup> by the end of the financial year. Planning for implementation for children with Type 1 diabetes is being finalised with the aim of providing access to all eligible children as soon as practicable.

FreeStyle Libre<sup>®</sup> comes at a significant cost to NHS Grampian and therefore the Grampian Diabetes Managed Clinical Network Devices Subgroup have developed some very clear criteria for eligibility, continuation and discontinuation and most importantly the patient responsibilities that must be met to be provided with this device.

In addition, in order to help pay for the additional costs of FreeStyle Libre<sup>®</sup>, NHS Grampian and the Diabetes Managed Clinical Network have agreed to work together to implement a number of efficiency projects to offset the costs of FreeStyle Libre<sup>®</sup>.

**For details about the criteria that need to be met to receive FreeStyle Libre<sup>®</sup> and how patients can register their interest to find out more and undertake training please see over-leaf.**

## FreeStyle Libre<sup>®</sup> - FAQs (Frequently asked questions)

### 1) Who will be eligible for FreeStyle Libre<sup>®</sup> in NHS Grampian?

It has been agreed to implement FreeStyle Libre<sup>®</sup> for the following people:

- a) Optimising glycaemic control using intensive insulin therapy for adults with Type 1 Diabetes

FreeStyle Libre<sup>®</sup> should only be used for people with Type 1 Diabetes Mellitus (T1DM) who have (all 3 criteria should be met):

- completed appropriate education (for example DAFNE, TIM or DIANE or equivalent level of education). N.B. insulin pump users will all have undertaken such training
- are proficient in carbohydrate counting.
- utilise intensive insulin treatment involving multiple daily insulin injections or insulin pump therapy

People will be asked to demonstrate that they have been monitoring their glucose levels at least 4 times a day to indicate that they are applying the principles of structured education appropriately as part of their consultations with the specialist care team. This will be assessed by reviewing their glucose monitoring downloads for the last 3 months.

- b) Supporting people with Type 1 Diabetes who have special needs or require assistance

FreeStyle Libre<sup>®</sup> may be appropriate for people with Type 1 Diabetes Mellitus who require someone other than themselves to perform glucose monitoring on their behalf. This may be due to poor dexterity or another disability and make conventional glucose testing and intensive insulin regimens difficult or impossible.

- c) Optimising glycaemic control using intensive insulin therapy for children with Type 1 Diabetes

FreeStyle Libre<sup>®</sup> is currently licensed for children 4 years or above. Children, young persons and their families will be expected to attend a FreeStyle Libre<sup>®</sup> training programme before a recommendation to use FreeStyle Libre<sup>®</sup> is made to their General Practitioner; i.e. no initiation will take place other than through the Diabetes Service.

The paediatric diabetes service has identified all Grampian children with Type 1 Diabetes treated through the service and will arrange for these children to be offered FreeStyle Libre<sup>®</sup> where they and/or their carers (as appropriate) meet the following criteria:

- completed appropriate structured education. N.B. insulin pump users will all have undertaken such training.

## **2) If I am eligible for FreeStyle Libre<sup>®</sup> what are the expectations on me before I start using the device and what are my responsibilities once I am using the FreeStyle Libre<sup>®</sup>?**

All people starting on FreeStyle Libre<sup>®</sup> are required to:

1. Attend a recognised diabetes structured education programme or suitable alternative agreed by the secondary care team to optimise glucose control if they have not attended one previously
2. Attend a locally provided Flash Glucose Monitoring education session
3. Scan glucose levels at least 6 times per day including at meal times and to ensure complete results are available for each 24-hour period and are using the information to optimise glucose levels
4. Share their glucose data with their secondary care diabetes clinic
5. Accept that continued availability of the sensors on prescription will depend on on-going effective use of the technology to improve self management as assessed (6 monthly in adults/ 3 monthly for paediatrics) by the secondary care diabetes specialist team
6. Sign a contract (implicit supported with information sheet) that outlines the criteria for initial and ongoing provision of FreeStyle Libre<sup>®</sup> by NHS Grampian
7. Agree to switch capillary (fingertip) blood glucose and ketone monitoring systems to the most cost effective choices
8. Agree to the discontinuation of FreeStyle Libre<sup>®</sup> if the criteria for continuation are not met and/or discontinuation criteria are met

## **3) Is FreeStyle Libre<sup>®</sup> accepted by the DVLA?**

FreeStyle Libre<sup>®</sup> is not currently accepted by the DVLA as a measure of blood glucose in relation to driving. Therefore drivers are still required to use (fingertip) blood glucose testing as defined by the [DVLA](#).

## **4) Who decides if I can get FreeStyle Libre<sup>®</sup>?**

Prescriptions for FreeStyle Libre<sup>®</sup> will only be issued on the recommendation of the secondary care diabetes centre. Once a patient has been assessed as meeting ALL the criteria for initiation, a letter recommending starting FreeStyle Libre<sup>®</sup> will be sent to the General Practitioner. On initiation patients will receive a FreeStyle Libre<sup>®</sup> reader and their first sensor from the specialist Diabetes Team. Subsequent sensors will be provided via prescription from the patient's General Practitioner.

## **5) How will FreeStyle Libre<sup>®</sup> use be monitored?**

Adults with Type 1 diabetes will be reviewed every six months and children with Type 1 diabetes every three months by their specialist diabetes clinician to ensure they are meeting their obligations for using FreeStyle Libre<sup>®</sup> and are continuing to benefit from the device. The specialist clinician should recommend ongoing use of FreeStyle Libre<sup>®</sup> based on evidence of continued benefit obtained as part of routine clinical review within

secondary care. It is expected that people would experience at least one of the following benefits:

- Reduction in episodes of severe hypoglycaemia
- Reduction in the proportion of time spent in hypoglycaemia
- Improvement in HbA1c of 5mmol / mol in 6 months
- Reduction in admissions to hospital
- Reduction in episodes of diabetic ketoacidosis (DKA)

#### **6) Under what circumstances might FreeStyle Libre® be stopped once it has been started?**

The specialist diabetes team will consider discontinuation if any one of the following occurs:

- Failure to attend follow up appointments
- Failure to scan at least enough to produce 80% of continuous glucose readings
- Failure to scan at meal times and use the data to adjust insulin doses
- Failure to share this data with their secondary care team
- Failure to engage with the secondary care team to optimise issues with glycaemic control
- Failure to use testing strips and sensors as recommended. N.B. this includes ongoing excessive use of either blood glucose testing strips or FreeStyle Libre® sensors.
- Evidence of greater harm than benefit on clinical and psychological health (e.g. increased frequency of hypos, increased psychological morbidity)

#### **7) Once FreeStyle Libre® has been agreed as appropriate for me how do I get it?**

The reader and first sensor will be provided at the FreeStyle Libre® training sessions and thereafter prescriptions for sensors would be from your General Practitioner (GP). This will be dependent on product availability from the manufacturer.

#### **8) What is my position if I have previously accessed FreeStyle Libre® via private prescription?**

It is recognised that a number of people with Type 1 diabetes will have initiated FreeStyle Libre® privately (i.e. self funded the cost of the device and sensor). No patient will be transferred to NHS prescription of FreeStyle Libre® unless they meet all of the NHS Grampian criteria for initiation. The same criteria regarding continuation of FreeStyle Libre® will apply to people previously self-funding FreeStyle Libre® as those listed for NHS initiation.

**9) If I believe I meet the criteria and am eligible for FreeStyle Libre<sup>®</sup>, how do I register an interest in attending the Freestyle Libre<sup>®</sup> education?**

People with Type 1 Diabetes Mellitus who meet ALL of the eligibility criteria listed below may register their interest by self-referring as detailed below. Please note self-registration of interest in receiving training will only be dealt with via email. Please don't phone the clinic reception, (insulin) pump administrator, DSN helpline or secretaries.

FreeStyle Libre<sup>®</sup> (FSL) should only be used for people with Type 1 Diabetes Mellitus (T1DM) who have (all 3 criteria should be met):

- completed appropriate education (for example DAFNE, TIM or DIANE or equivalent level of education). N.B. insulin pump users will all have undertaken such training.
- are proficient in carbohydrate counting
- utilise intensive insulin treatment involving multiple daily insulin injections or insulin pump therapy

People will be asked to demonstrate that they have been monitoring their glucose levels at least 4 times a day to indicate that they are applying the principles of structured education appropriately as part of their consultations with the specialist care team. This will be assessed by reviewing their glucose monitoring downloads for the last 3 months.

**Those attending clinics at David Anderson Building (ARI), Fraserburgh Hospital or Kincardine Hospital:** Please get in touch using email: [nhsg.flashmonitoring@nhs.net](mailto:nhsg.flashmonitoring@nhs.net). You will receive an automated response detailing the next steps for self-referral. This email address should not be used for any other enquiries.

**Those attending clinics at Dr Gray's Hospital diabetes clinic or the hospital lead clinic at Forres and Seafeld Hospital (Buckie)**

Please get in touch using email: [nhsg.dghdiabetes@nhs.net](mailto:nhsg.dghdiabetes@nhs.net).

**For young people with Type 1 diabetes who are attending clinics at the Royal Aberdeen Children's Hospital or Dr Gray's Hospital or have not yet been seen in the Young Person's clinics:**

The Paediatric Diabetes team will be announcing in the very near future the steps to follow for those interested in using flash glucose monitoring. In the meantime we will not be replying to individual enquiries. Please download our App (<https://app.piota.co.uk/grampianchildrensdiabetes/>) for further announcements.

**If you are not currently attending the above clinics please discuss with your GP regarding referral to one of the hospital based clinics.** Please note your GP will not prescribe FreeStyle Libre<sup>®</sup> without you seeing the Diabetes Service, being assessed as eligible for FreeStyle Libre<sup>®</sup> including completion of the required training.

**If you don't currently meet the criteria for FreeStyle Libre<sup>®</sup>** we suggest that you discuss flash glucose monitoring and other support available to help improve your diabetes management at your next appointment.