NHS GG&C Introduction of Freestyle Libre ® flash glucose monitoring system

The Freestyle Libre® flash glucose monitoring system is a sensor based, factory-calibrated system that measures interstitial fluid (not blood) glucose levels in people (aged 4 years and over) with diabetes mellitus, including pregnant women.

In January 2018, the Scottish Diabetes Managed Clinical Network Lead Clinicians issued a position statement on the use of Freestyle Libre® flash glucose monitoring system, which was considered by the NHS GG&C Prescribing Management Group at their meeting on the April 2018.
It was agreed to make Freestyle Libre® available for use in NHS GG&C, as per the recommendations in this January 2018 position statement, until the Scottish Health Technologies Group (SHTG) within Healthcare Improvement Scotland issue their guidance in June 2018, and at which time the NHS GG&C position will be reconsidered.

Recommendations for use of Freestyle Libre® in NHS Greater Glasgow & Clyde

- Only secondary care diabetes teams can initiate patients on Freestyle Libre®.
- Freestyle Libre® will only be considered for use for people with Type 1 Diabetes Mellitus who:
  - are attending secondary care diabetes centres
  - are using multiple daily insulin injections (basal bolus) or insulin pump therapy,
  - have been assessed by the specialist clinician and are deemed to meet one or more of the criteria in the Scottish Diabetes Managed Clinical Network Lead Clinicians position statement on the use of Freestyle Libre® flash glucose monitoring system, January 2018. (Appendix 1)
- Patients currently "self-funding" must meet the above criteria and be assessed by a secondary care specialist clinician to be eligible for NHS funding.
- Patients with type 1 diabetes who meet the criteria are currently attending a hospital diabetes clinic (adults, pregnancy and paediatrics) will be contacted directly by secondary care teams regarding the Freestyle Libre®.

Responsibilities of secondary care diabetes teams

- Assess patient's eligibility for the use of Freestyle Libre®, as per the Scottish Diabetes Managed Clinical Network Lead Clinicians position statement.
- Discuss with people with type 1 diabetes the commitment required for trial and on-going funding of Freestyle Libre®.
- Advise patients to complete the online training at Libre Academy: to facilitate this as necessary.
- Provide patient education sessions on Freestyle Libre® and education material.
- Provide the person with a Freestyle Libre® meter and first sensor.
- Advise the patient's General Practitioner of the patient's eligibility for Freestyle Libre® and advising on issuing prescriptions for sensors and blood glucose test strips**.**
- Assess on-going eligibility for continued funding of Freestyle Libre® (6 monthly for adults/ 3 monthly for paediatrics).
- Participate in multi-disciplinary discussion and sharing experience.
- To ensure SCI-Diabetes is updated at start and relevant data (HbA1c, questionnaires) is collected.
- Commit to audit local data and contribute to Scottish/UK wide audit.

Responsibility of the person established as being eligible for Freestyle Libre®

- Agree to attend a locally provided Flash Glucose Monitoring education session; **and**
- Agree to scan glucose levels no less than six times per day; **and**
- Agree to share glucose data with their diabetes clinic and complete any clinical and quality of life questionnaires.
- Attend a recognised diabetes structured education programme (eg DAFNE) and/or the clinical team are satisfied that the person (or carer) has required knowledge/skills to self-manage diabetes.
- Aware that the continued availability (assessed 6 monthly in adults/ 3 monthly for Paediatrics) by secondary care diabetes specialist) will depend on on-going effective use of the technology to improve self-management.
- Aware that they will receive no more than 2 - 4 sensors at any one time and no more than 26 sensors per annum (unless there are exceptional circumstances).

Responsibilities of General Practitioners

- Do not prescribe Freestyle Libre® sensors for any patient unless they have been deemed as meeting the access criteria by the secondary care diabetes service, including patients who are currently "self funding" and correspondence has been received from the service.
- Refer any patient with type 1 diabetes who is not currently attending a hospital diabetes clinics, to the secondary care diabetes service (adult or paediatric) that are requesting to be considered for the Freestyle Libre®.
- Prescribe ongoing Freestyle Libre® sensors (recommended that **no more than 2 - 4 sensors are provided at any one time and no more than 26 sensors per annum** (unless there are exceptional circumstances)).
- Prescribe blood glucose test strips, as recommended by the secondary care diabetes teams which will still be required, such as when a person is unwell (scanned readings are at the extremes of glycaemia) or to meet the requirements of the Driver and Vehicle Licensing Agency in assessing fitness to drive.
- The MCN support the 2018 NHS GG&C Blood Glucose & Ketone Meter formulary for use in adults and its implementation.

NHSGGC Freestyle Libre Implementation Plan

Adults - People, within our adult services, who have impaired awareness of hypoglycaemia/patients already identified at each site as a clinical priority will be contacted in the first instance thereafter eligible people will be identified in clinic. A letter will be sent to those eligible to receiving NHS funding for FreeStyle Libre® to invite them to attend an education event. Following attendance at the education session a letter from the Diabetes MCN will be sent to the persons GP to advise that they have completed all of the necessary requirements and that Freestyle Libre can now be prescribed.

Pregnancy - People who are either planning a pregnancy or are pregnant will be identified through their attendance at our diabetes pregnancy clinics. Education will be provided by the local teams and thereafter, a letter from the pregnancy team will be sent to the persons GP to advise that they have completed all of the necessary requirements and that Freestyle Libre can now be prescribed.

Children – All eligible people within our children's services will have received a letter inviting interested people to attend an education event. Following attendance at the education session, one sensor will be provided (last two weeks) and a letter from the Children's Diabetes Service will be sent to the persons GP to advise that they have completed all of the necessary requirements and that Freestyle Libre can now be prescribed.

Appendix 1

Use of Freestyle Libre® flash glucose monitoring system
Diabetes Managed Clinical Network Lead Clinicians Position Statement January 2018

A. Introduction.

The Diabetes Managed Clinical Network (MCN) lead clinicians from across Scotland were asked to develop further guidance on the use of flash glucose monitoring system Freestyle Libre® within NHS Scotland. This guidance has considered the advice provided by the Scottish Diabetes Group, the Association of British Clinical Diabetologists (ABCD), Diabetes UK, NICE and existing submissions from diabetes MCNs to health boards across Scotland. In an attempt to ensure a consistent approach across the UK we have also considered the position statement from the four Regional Medicines Optimisation Committee's for England, the consensus statements from NHS Wales and the Diabetes Network for Northern Ireland.

It is also important to consider the current position of flash blood glucose monitoring within the evolving field of technologies to manage diabetes as it is anticipated that within 5 years the management of type 1 diabetes will be revolutionised with the availability of the bionic pancreas – anticipated to be licensed in Europe in 2019. This means that the use of the device described below may then be superseded by more complex devices which will essentially provide a technological "cure" for the management of glycaemia in type 1 diabetes.

B. Brief Description of the Freestyle Libre® device.

The Freestyle Libre® flash glucose monitoring system is a sensor based, factory-calibrated system that measures interstitial fluid (not blood) glucose levels in people (aged 4 years and over) with diabetes mellitus, including pregnant women. As detailed within the advice from Diabetes UK and endorsed by ABCD this device provides a unique potential to vastly improve the quality of life for patients with diabetes as it reduces the need for painful finger stick blood tests.

C. Recommendations for Use

It is recommended that the Freestyle Libre®(FSL) should only be used for people with Type 1 DM(T1DM) who are attending secondary care diabetes centres who are using multiple daily insulin injections (basal bolus) or insulin pump therapy, who have been assessed by the specialist clinician and are deemed to meet one or more of the following:-

1. Patients who undertake intensive monitoring with a minimum of 6 tests per day.
2. Impaired awareness of hypoglycaemia but not those with persistent hypoglycaemic unawareness where continuous glucose monitoring (CGM) is the required therapeutic intervention.
3. Frequent admissions (>2 per year) with DKA or hypoglycaemia.
4. Those who require a third party to perform monitoring or where dexterity or disability denote that conventional testing is difficult or impossible.
5. Those who meet the current NICE criteria for insulin pump therapy (HbA1c >8.5% [69.4mmol/mol] or disabling hypoglycaemia described in NICE TA151) where a successful trial of FSL may avoid the need for pump therapy.
6. Women who are either planning a pregnancy or are pregnant.

Diabetes MCNs and diabetes teams will consider the above 'Recommendations for Use' and initiate FSL based on clinical need within those patient cohorts. Those individuals who currently 'self-fund' should meet the above criteria to be eligible for NHS funding.

The recommendation to commence Freestyle Libre should originate from a secondary care diabetes specialist/team. Prescriptions for Freestyle Libre sensors (like blood glucose test strips) should be issued by the patient's primary care provider.

In addition, a supply of finger-prick blood glucose measurements will still be needed, such as when a person is unwell, scanned readings are at the extremes of glycaemia or to meet the requirements of the Driver and Vehicle Licensing Agency in assessing fitness to drive.

Once eligibility is established the person with diabetes must:

1. Agree to attend a locally provided Flash Glucose Monitoring education session; and
2. Agree to scan glucose levels no less than six times per day; and
3. Agree to share glucose data with their diabetes clinic and complete any clinical and quality of life questionnaires;
4. Have attended a recognised diabetes structured education programme and/or the clinical team are satisfied that the person (or carer) has required knowledge/skills to self-manage diabetes.
5. Awareness that continued availability (assessed 6 monthly in adults/3 monthly for Paediatrics) by secondary care diabetes specialist) will depend on on-going effective use of the technology to improve self-management.
6. Aware that they will receive no more than 26 sensors per annum (unless there are exceptional circumstances).

Specialist Diabetes Teams will ensure:

1. Eligibility criteria are adhered to
2. Discussion with people with type 1 diabetes the commitment required for trial and on-going funding of Freestyle Libre
3. Educational sessions are set up and once people with diabetes have attended, their General Practitioner(s) are advised to issue prescription for Freestyle Libre
4. Assess on-going eligibility for continued funding of Freestyle Libre (6 monthly for adults/ 3 monthly for paediatrics)
5. Multi-disciplinary discussion and sharing experience
6. SCI-Diabetes updated at start and relevant data (HbA1c, questionnaires) is collected
7. Commitment to audit local data and contribute to Scottish/UK wide audit.

D. Recommendations for Continuation.

The specialist clinician should recommend ongoing use of FSL, based on evidence of continued benefit obtained as part of routine clinical review (6 monthly) within secondary care. Each patient would need to demonstrate benefit in one or more of the following over a 12 month period:

1. Continuation Criteria

- Reduction in episodes of DKA.
- Reduction in admissions to hospital.
- Reduction in episodes of severe hypoglycaemia.
- Reduction in the proportion of time spent in hypoglycaemia.
- Reversal of impaired awareness of hypoglycaemia.
- Improvement in HbA1c of 5 mmol/mol in 6 months.

2. Discontinuation Criteria any one of the following:

- Failure to achieve at least one of the criteria listed in the section above.
- Failure to attend follow up appointments.
- Failure to scan at least six times per day.
- Failure to share this data with their secondary care team.
- Failure to engage with secondary care team to optimise issues with glycaemic control.
- Failure to use testing strips and sensors as recommended.
- Evidence of greater harm than benefit on clinical and psychological health (eg increased frequency of hypos, increased psychological morbidity).

E. Children

For guidance refer to the NICE guidelines on CGM in children and the English, BSPED endorsed, CGM guidelines: http://www.bsped.org.uk/clinical/clinical_endorsedguidelines.aspx.
FSL is currently licensed for children 4 years or above. The above pre-requisites, continuation and discontinuation criteria apply to children. Children, young persons and their families will be expected to attend a FSL training programme before a recommendation is made to their primary care team.

F. Provision of sensors

The SDG recommends no more than 26 sensors per annum. It would be recommended that GPs should not prescribe more than 2-4 at a time and that it is up to the patient to check that sensors do not go out of date before they have an opportunity to use them.

The meter and first sensor will be provided by the company and given to patients at the training sessions and thereafter prescriptions would be from the GP.

G. Audit / Evaluation.

The group endorsed the view that it is imperative that there is ongoing, detailed audit surrounding the roll out of Freestyle Libre®. It is therefore essential that its use in NHS Scotland is recorded on SCI Diabetes so that collaborative research within NHS Scotland and with ABCD support in the UK describes the clinical benefit in people with T1DM. This information will also help inform the ongoing Scottish Health Technology Group assessment of flash blood glucose monitoring-

Audit Data collection would include:

1. Reductions in severe/non-severe hypoglycaemia
2. Reversal of impaired awareness of hypoglycaemia
3. Episodes of diabetic ketoacidosis
4. Admissions to hospital
5. Changes in HbA1c
6. Quality of Life changes using validated rating scales.
7. Commitment to regular scans and their use in self-management.

H. References.

NICE Medtech Innovation Briefing [MIB 110]: FreeStyle Libre® for glucose monitoring NICE July 2017. Available at https://www.nice.org.uk/advice/mib110

ABCD Type 1 Diabetes Clinical Collaborative: Information to help a formulary case for Freestyle Libre System October 2017. Available at https://abcd.care/getting-freestyle-libre-your-formulary

Diabetes UK. Diabetes Facts and Stats Version 4 Revised October 2016. via https://www.diabetes.org.uk/Documents/Position%20statements/DiabetesUK_Facts_Stats_Oct16.pdf

Regional Medicines Optimisation Committee Flash Glucose Monitoring Systems Position Statement. Via https://www.sps.nhs.uk/wp-content/uploads/2017/11/Flash-Glucose-monitoring-System-RMOC-Statement-final-2.pdf