Protocol for initiating FreeStyle Libre® for glucose monitoring

In ADULTS

FreeStyle Libre® is a flash glucose monitoring (Flash GM) system which monitors glucose levels using interstitial fluid levels rather than capillary blood glucose from finger prick testing. Interstitial glucose levels are not quite the same as blood glucose levels, glucose levels in the blood rise and fall ahead of glucose levels in the interstitial fluid.

Use of FreeStyle Libre should reduce the frequency of finger prick monitoring to measure blood glucose levels, however, blood glucose levels should still be taken:

- When interstitial glucose levels are rapidly changing (due to the time lag between blood glucose and interstitial glucose levels)
- To meet Driving and Vehicle Licensing Authority (DVLA) requirements
- When scanned glucose results do not meet with the users symptoms
- To use the bolus calculator function
- When the reader indicates a low glucose reading, i.e. <4mmol/L

Adjunct blood testing strips should be prescribed according to locally agreed best value guidelines with an expectation that demand/frequency of supply will be reduced.

Audit data on the use of FreeStyle Libre® should be collected through its use in limited and controlled settings where patients are attending for Type 1 diabetes care.

In Barnsley, the following principles have been used to guide the initiation and supply of FreeStyle Libre®:

- FreeStyle Libre® can only be initiated in adult patients with Type 1 diabetes, according to the patient selection criteria below (for children – see separate guidance); or for patients with any form of diabetes receiving haemodialysis and requiring insulin therapy; or for patients with diabetes associated with cystic fibrosis requiring insulin therapy.
- FreeStyle Libre® can only be initiated by the diabetes specialist team.
- The diabetes specialist team will initiate and provide a supply for the first 3 months of use. During the first 3 months of use, regular review is essential to ensure patients are engaged with the use of the device. Anecdotal reports suggest that a number of patients are unable to use the device for a variety of reasons.
- The diabetes specialist team will monitor the agreed outcomes as specified in the monitoring of outcomes section below.
- Transfer of prescribing to primary care will only occur if:
    - The patient selection is appropriate.
    - The patient is engaged with training on the device and is committed to regular follow ups and ongoing monitoring.
    - An improvement in the required outcomes has been achieved.

Roles and Responsibilities

Specialist Responsibilities

- Patient is assessed and is deemed to be suitable for initiation of FreeStyle Libre®.
- Patient/patient's carer is educated (either online or in person) on the use of FreeStyle Libre® and is provided with the monitoring device and an initial supply of sensors. The specialist team will counsel the patient on safe disposal of sensors. Sensors must be disposed of in a sharps bin (it is recommended that a large sharps bin e.g. 5 litre is used as the sensors do not fit through the opening of the 1 litre sharps bin).
- Patient is reviewed by the diabetes specialist team regularly for the first 3 months of use (at least 3 monthly) and is assessed on their use of FreeStyle Libre®. A full record of the review is made and is communicated to primary care (including information relating to outcomes). The FreeStyle Libre® sensors must be supplied by the specialist team for at least the first 3 months of use.
- If improved outcomes have been achieved, GPs will be approached at a minimum of 3 months to take on prescribing. The proforma in Appendix A must be completed.
- The patient will be reviewed regularly by the specialist team. The time between each review will depend on the patient but at a minimum will be reviewed once a year.
- The specialist team will counsel the patient on circumstances where capillary blood glucose monitoring is required in addition to Flash Glucose monitoring and will clarify that capillary monitoring is not routinely required except in these circumstances.

GP/Clinical Pharmacist Responsibilities

- Patient has been assessed by the specialist team and is deemed to be suitable for initiation of FreeStyle Libre®.
- Patient has been using FreeStyle Libre® for a minimum of three months and it has been shown to improve the patient outcomes.
- Specialist has written to the GP/Clinical Pharmacist using the proforma in Appendix A. detailing the reasons why FreeStyle Libre® has been initiated and the improvement in outcomes that has been achieved.
- GP/Clinical Pharmacist to continue prescribing FreeStyle Libre® sensors in primary care.
- Patient will be reviewed by the specialist team at least annually.
- GP to prescribe replacement sharps bins for the disposal of sensors, as required (it is recommended that a large sharps bin e.g. 5 litre is used as the sensors do not fit through the opening of the 1 litre sharps bin) and to provide the patient with a list of Barnsley sharps bin disposal locations. The list of sharps bin disposal locations is available on the BEST website at the following link:
  http://best.barnsleyccg.nhs.uk/clinical-support/local-pathways-and-guidelines/MSK%20and%20Derm/rheumatology%20advice%20numbers/Sharps%20bin%20disposal.pdf.
  Replacement sharps bins are available from the sharps bin disposal locations.

Patient Responsibilities

- Patient/patient's carer will undergo training on the use of FreeStyle Libre®.
- Previous attendance or due consideration given to future attendance at a Type 1 diabetes structured education programme (e.g. DAFNE)
- Patient will commit to ongoing regular follow-up and monitoring with the specialist diabetes team and will be committed to using the FreeStyle Libre® device.
- The FreeStyle Libre® will no longer be prescribed if an improvement in outcomes has not been achieved or the patient becomes disengaged with use of the device.
- Patient agrees to scan glucose levels no less than eight times a day and will use the sensor over 70% of the time.

Monitoring of Outcomes

Patients started on FreeStyle Libre® should be monitored regularly in order to assess whether the device is suitable for them and that use is leading to improved outcomes. The following outcomes should be monitored where applicable:

- Reductions in severe/non-severe hypoglycaemia
- Reversal of impaired awareness of hypoglycaemia
- Episodes of diabetic ketoacidosis
- Admissions to hospital
- Changes in HbA1c (see criteria for stopping above)
- Testing strip usage
- For adults, Quality of Life changes using validated rating scales (See Appendix B).
- Commitment to regular scans and their use in self-management.

Patient Selection: Adults

The following patient groups will be eligible for Flash Glucose monitoring:

- Patients with diabetes associated with cystic fibrosis requiring insulin therapy.
- Patients with Type 1 diabetes or with any form of diabetes on haemodialysis and on insulin treatment and clinically indicated as requiring intensive monitoring >8 times daily as demonstrated on a meter download/review over the past 3 months (applies to both of these patient groups).

For patients with Type 1 diabetes, one or more of the following criteria must also be satisfied:

1. Patients who undertake intensive monitoring >8 times daily as demonstrated on meter download or review over the past three months.
2. Type 1 diabetes patients on basal bolus or pump therapy with sub optimal control i.e. HbA1c> 69mmol/mol (8.5%) but <85mmol/mol (>85mmol/mol is an indication that insulin is not being used regularly), DAFNE trained and engaging in self-management , i.e. testing on average 4 times a day for 3 months as evidenced by a meter download.
3. Planning pregnancy or pregnant (hypoglycaemia awareness is reduced in pregnancy). Flash Glucose Monitoring is suitable for 12 months in total including the post delivery period.
4. Patients unable to routinely self-monitor due to disability who require carers to support glucose monitoring and insulin management.
5. People with Type 1 Diabetes for whom the specialist diabetes MDT determines that they have occupational (e.g. working in insufficiently hygienic conditions to safely facilitate finger-prick testing) or psychosocial circumstances that warrant a 6 month trial of Freestyle Libre® with appropriate adjunct support.
6. Disabling hypoglycaemia. NICE TA151 described disabling hypoglycaemia as the repeated and unpredictable occurrence of hypoglycaemia that results in persistent anxiety about recurrence and is associated with a significant adverse effect on quality of life.
7. Frequent admissions (>2 per year) with DKA or hypoglycaemia.
8. Patients already self-funding should meet the criteria above **prior** to first initiation. They must also be showing improvement in HBA1c since self-funding.
9. Rarities of spontaneous hypoglycaemia e.g. Insulin secreting tumour

- FreeStyle Libre® could be considered for exercise in adults in the following circumstances:

    - For those competing or exercising regularly. It can be used to optimise carbohydrate and insulin adjustment before, during and after exercise to maximise the effect of exercise on improving diabetes control and ensure that sporting performance is optimised.

    - For those trying to lose weight but fearful of the hypoglycaemic effects of exercise.

    - For those who have had a severe episode of hypoglycaemia following sporting activity and cannot resume activity.

    - For those in whom there is concern regarding overcompensation with additional carbohydrate for activity.

    - Those involved in high endurance sporting activities where it is difficult to test blood sugar.

    - For those where exercise results in unpredictable hypoglycaemia.

Groups not suitable

- Individuals with total hypoglycaemia unawareness or recurrent and severe hypoglycaemia. NICE recommends a continuous glucose monitoring system that contains an alarm function. FreeStyle Libre® does not have this. However, clinicians may consider FreeStyle Libre® for certain patients in this group if other options are unsuitable.

- Individuals with HbA1c >85mmol/mol (indicating not giving insulin regularly each day).

Criteria for stopping

- Patients with a baseline HbA1c**<70mmol/mol** (8.6%) - if a 5mmol/mol drop by 3 months is not achieved **or** a significant reduction in time spent in hypoglycaemia is not achieved. If reduction is not maintained at 6 months.

- Patients with a baseline HbA1c**≥70mmol/mol** (8.6%) **-** if a 10mmol/mol drop by 3 months is not achieved. If reduction is not maintained at 6 months.

- For those previously self-funding, blood glucose levels not at target for the majority of time, HbA1c >58mmol/mol (7.5%), or >10% of reading under 4mmol/L

- Not up to date with the 9 care processes (see Appendix B)

- Patient is not engaging with the specialist team on a regular basis

Development Process: *This information has been subject to consultation and endorsement by the Endocrinologists in Barnsley and was ratified by the Area Prescribing Committee on 14th August 2019.*

APPENDIX A

ADULTS

Proforma for transfer of prescribing to primary care

- Specialist to complete when requesting GP to take over prescribing of FreeStyle Libre®.
- GP to return signed copy of form.
- Both parties should retain a signed copy of the form in the patient's record.

From (**Specialist**): _____ **To** (**GP**): _____

Patient details

Name: _____ ID Number: _____

Address: _____ DOB: _____

The patient will be reviewed by the specialist team on: _____

Specialist name: _____ Telephone number(s): _____

Patient selection criteria

(Please state which of the criteria below apply)

Criteria	**Yes / No**
Patient with diabetes associated with cystic fibrosis requiring insulin therapy	
Patient with Type 1 Diabetes and undertaking intensive monitoring >8 times daily	
Patient with any form of diabetes and on haemodialysis and requiring intensive monitoring >8 times daily	
Type 1 diabetes patients on basal bolus or pump therapy with sub optimal control i.e. HbA1c> 69mmol/mol (8.5%) but <85mmol/mol (>85mmol/mol indicates not giving insulin regularly)	
Planning pregnancy or pregnant	
Patients unable to routinely self-monitor due to disability who require carers to support glucose monitoring and insulin management.	
Patient with impaired awareness of hypoglycaemia	
Patient has frequent admissions (>2 per year) with DKA or hypoglycaemia	

Patients already self-funding should meet the criteria above **prior** to first initiation. They must also be achieving an improvement in HbA1c since self-funding.	
Rarities of spontaneous hypoglycaemia e.g. Insulin secreting tumour	
Exercise in adults in the following circumstances: • Competing / exercising regularly to optimise carbohydrate and insulin adjustment before, during and after exercise to maximise the effect of exercise on improving diabetes control and ensure that sporting performance is optimised. • For adults trying to lose weight but fearful of the hypoglycaemic effects of exercise • For those who have had a severe episode of hypoglycaemia following sporting activity and cannot resume activity • For those in whom there is concern regarding overcompensation with additional carbohydrate for activity • Those involved in high endurance sporting activities where it is difficult to test blood sugar • For those where exercise results in unpredictable hypoglycaemia	

Outcomes Monitoring

The following outcomes should be monitored. Details of baseline values and values at 3 months should be included.

Parameter	**Baseline**	**At 3 months**	**Improvement?** **(Y/N)**
Frequency of severe/non-severe hypoglycaemia			
Does the patient have an impaired awareness of hypoglycaemia?			
Frequency of episodes of diabetic ketoacidosis			
Frequency of admissions to hospital			
HbA1c level • If baseline HbA1c**<70mmol/mol** (8.6%) – need a 5mmol/mol drop by 3 months • If baseline HbA1c**≥70mmol/mol** (8.6%) **–** need a 10mmol/mol drop by 3 months			
Level of test strip usage			
Is patient up to date with the 9 processes of care?			
Quality of Life score using validated rating scales			
Has the patient used FreeStyle Libre in an appropriate way? I.e. Commitment to regular scans and their use in self-management			

Confirmation of acceptance from GP

The patient has met the criteria for the initIation of FreeStyle Libre® and has achieved the required outcomes listed above to continue with use of the device. Specialist to sign below:

Specialist (Doctor/Nurse) name: _____

Specialist (Doctor/Nurse) signature: _____ Date: _____

I, Dr ……., can confirm I :

- □ Accept the request to prescribe FreeStyle Libre® for the patient named above.
- □ Reject the request to prescribe FreeStyle LIbre® for the patient named above. The reason for this being ……..

GP signature: _____ Date: _____

APPENDIX B

Diabetes Self-Management Questionnaire (DSMQ)

The following statements describe self-care activities related to your diabetes. Thinking about your self-care over the last 8 weeks, please specify the extent to which each statement applies to you.		**Applies to me very much**	**Applies to me to a consider-able degree**	**Applies to me to some degree**	**Does not apply to me**
1.	I check my blood sugar levels with care and attention. ☐ *Blood sugar measurement is not required as a part of my treatment.*	☐3	☐2	☐1	☐0
2.	The food I choose to eat makes it easy to achieve optimal blood sugar levels.	☐3	☐2	☐1	☐0
3.	I keep all doctors' appointments recommended for my diabetes treatment.	☐3	☐2	☐1	☐0
4.	I take my diabetes medication (e. g. insulin, tablets) as prescribed. ☐ *Diabetes medication / insulin is not required as a part of my treatment.*	☐3	☐2	☐1	☐0
5.	Occasionally I eat lots of sweets or other foods rich in carbohydrates.	☐3	☐2	☐1	☐0

The following statements describe self-care activities related to your diabetes. Thinking about your self-care over the last 8 weeks, please specify the extent to which each statement applies to you.		**Applies to me very much**	**Applies to me to a consider-able degree**	**Applies to me to some degree**	**Does not apply to me**
6.	I record my blood sugar levels regularly (or analyse the value chart with my blood glucose meter). ☐ *Blood sugar measurement is not required as a part of my treatment.*	☐3	☐2	☐1	☐0
7.	I tend to avoid diabetes-related doctors' appointments.	☐3	☐2	☐1	☐0
8.	I do regular physical activity to achieve optimal blood sugar levels.	☐3	☐2	☐1	☐0
9.	I strictly follow the dietary recommendations given by my doctor or diabetes specialist.	☐3	☐2	☐1	☐0
10.	I do not check my blood sugar levels frequently enough as would be required for achieving good blood glucose control. ☐ *Blood sugar measurement is not required as a part of my treatment.*	☐3	☐2	☐1	☐0

The following statements describe self-care activities related to your diabetes. Thinking about your self-care over the last 8 weeks, please specify the extent to which each statement applies to you.		**Applies to me very much**	**Applies to me to a consider-able degree**	**Applies to me to some degree**	**Does not apply to me**
11.	I avoid physical activity, although it would improve my diabetes.	☐3	☐2	☐1	☐0
12.	I tend to forget to take or skip my diabetes medication (e. g. insulin, tablets). ☐ *Diabetes medication / insulin is not required as a part of my treatment.*	☐3	☐2	☐1	☐0
13.	Sometimes I have real 'food binges' (not triggered by hypoglycaemia).	☐3	☐2	☐1	☐0
14.	Regarding my diabetes care, I should see my medical practitioner(s) more often.	☐3	☐2	☐1	☐0
15.	I tend to skip planned physical activity.	☐3	☐2	☐1	☐0

Schmitt, A., Gahr, A., Hermanns, N., Kulzer, B., Huber, J. and Haak, T. (2017). The Diabetes Self-Management Questionnaire (DSMQ): development and evaluation of an instrument to assess diabetes self-care activities associated with glycaemic control.

APPENDIX C

The nine processes of care:

- Weight
- Blood pressure
- Smoking status
- HbA1c
- Urinary albumin
- Serum creatinine
- Cholesterol
- Eye examinations
- Foot examinations