

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)
- FreeStyle Libre® can only be initiated by the diabetes specialist team
- The diabetes specialist team will initiate and provide a supply for the first 6 months of use. During the first 6 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 on the use of FreeStyle Libre® and is provided with the monitoring device and an initial supply of sensors.
- Patient is reviewed by the diabetes specialist team regularly for the first 6 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 6 months of use.
- If improved outcomes have been achieved, GPs will be approached at a minimum of 6 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.

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 six 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.

Patient Responsibilities

- Patient/patient's carer will undergo training on the use of FreeStyle Libre®.
- 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.

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

Patients with Type 1 diabetes attending specialist Type 1 care using multiple daily injections or insulin pump therapy, who have been assessed by the specialist clinician and are willing to engage with the specialist team on a regular basis, as evidenced by regular appointment attendance, diary completion, baseline and follow-up assessment of HbA1c etc. Ongoing self-care and management as evidenced by all 9 care processes being up to date (see Appendix C).

PLUS one or more of the following:

1. Patients who undertake intensive monitoring >8 times daily
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)
4. 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.
5. Frequent admissions (>2 per year) with DKA or hypoglycaemia.
6. Patients already self-funding should meet the criteria above **prior** to first initiation. They must also be achieving an HbA1c of <59mmol/mol (7.5%), blood glucose in target most of the time, with <10% of readings under 4 mmol/L.
7. Rarities of spontaneous hypoglycaemia e.g. Insulin secreting tumour

Groups not suitable

- Individuals with total hypoglycaemia unawareness. NICE recommends a continuous glucose monitoring system that contains an alarm function. FreeStyle Libre® does not have this.
- 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 11th April 2018.

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 undertakes 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	
Patient with impaired awareness of hypoglycaemia	
Patient has frequent admissions (>2 per year) with DKA or hypoglycaemia	
Patients already self-funding and achieving an HbA1c of <59mmol/mol (7.5%), blood glucose in target most of the time, with <10% of readings under 4 mmol/L, as long as the patient met the criteria above prior to first initiation	
Rarities of spontaneous hypoglycaemia e.g. Insulin secreting tumour	

Outcomes Monitoring

The following outcomes should be monitored. Details of baseline values and values at 6 months should be included.

Parameter	Baseline	At 6 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 <ul style="list-style-type: none"> • 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			

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

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 considerable degree	Applies to me to some degree	Does not apply to me
1.	I check my blood sugar levels with care and attention. <input type="checkbox"/> <i>Blood sugar measurement is not required as a part of my treatment.</i>	<input type="checkbox"/> 3	<input type="checkbox"/> 2	<input type="checkbox"/> 1	<input type="checkbox"/> 0
2.	The food I choose to eat makes it easy to achieve optimal blood sugar levels.	<input type="checkbox"/> 3	<input type="checkbox"/> 2	<input type="checkbox"/> 1	<input type="checkbox"/> 0
3.	I keep all doctors' appointments recommended for my diabetes treatment.	<input type="checkbox"/> 3	<input type="checkbox"/> 2	<input type="checkbox"/> 1	<input type="checkbox"/> 0
4.	I take my diabetes medication (e.g. insulin, tablets) as prescribed. <input type="checkbox"/> <i>Diabetes medication / insulin is not required as a part of my treatment.</i>	<input type="checkbox"/> 3	<input type="checkbox"/> 2	<input type="checkbox"/> 1	<input type="checkbox"/> 0
5.	Occasionally I eat lots of sweets or other foods rich in carbohydrates.	<input type="checkbox"/> 3	<input type="checkbox"/> 2	<input type="checkbox"/> 1	<input type="checkbox"/> 0

<p>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.</p>	<p>Applies to me very much</p>	<p>Applies to me to a considerable degree</p>	<p>Applies to me to some degree</p>	<p>Does not apply to me</p>
<p>6. I record my blood sugar levels regularly (or analyse the value chart with my blood glucose meter).</p> <p><input type="checkbox"/> <i>Blood sugar measurement is not required as a part of my treatment.</i></p>	<p><input type="checkbox"/>3</p>	<p><input type="checkbox"/>2</p>	<p><input type="checkbox"/>1</p>	<p><input type="checkbox"/>0</p>
<p>7. I tend to avoid diabetes-related doctors' appointments.</p>	<p><input type="checkbox"/>3</p>	<p><input type="checkbox"/>2</p>	<p><input type="checkbox"/>1</p>	<p><input type="checkbox"/>0</p>
<p>8. I do regular physical activity to achieve optimal blood sugar levels.</p>	<p><input type="checkbox"/>3</p>	<p><input type="checkbox"/>2</p>	<p><input type="checkbox"/>1</p>	<p><input type="checkbox"/>0</p>
<p>9. I strictly follow the dietary recommendations given by my doctor or diabetes specialist.</p>	<p><input type="checkbox"/>3</p>	<p><input type="checkbox"/>2</p>	<p><input type="checkbox"/>1</p>	<p><input type="checkbox"/>0</p>
<p>10. I do not check my blood sugar levels frequently enough as would be required for achieving good blood glucose control.</p> <p><input type="checkbox"/> <i>Blood sugar measurement is not required as a part of my treatment.</i></p>	<p><input type="checkbox"/>3</p>	<p><input type="checkbox"/>2</p>	<p><input type="checkbox"/>1</p>	<p><input type="checkbox"/>0</p>

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 considerable degree	Applies to me to some degree	Does not apply to me
11.	I avoid physical activity, although it would improve my diabetes.	<input type="checkbox"/> 3	<input type="checkbox"/> 2	<input type="checkbox"/> 1	<input type="checkbox"/> 0
12.	I tend to forget to take or skip my diabetes medication (e. g. insulin, tablets). <input type="checkbox"/> <i>Diabetes medication / insulin is not required as a part of my treatment.</i>	<input type="checkbox"/> 3	<input type="checkbox"/> 2	<input type="checkbox"/> 1	<input type="checkbox"/> 0
13.	Sometimes I have real ‘food binges’ (not triggered by hypoglycaemia).	<input type="checkbox"/> 3	<input type="checkbox"/> 2	<input type="checkbox"/> 1	<input type="checkbox"/> 0
14.	Regarding my diabetes care, I should see my medical practitioner(s) more often.	<input type="checkbox"/> 3	<input type="checkbox"/> 2	<input type="checkbox"/> 1	<input type="checkbox"/> 0
15.	I tend to skip planned physical activity.	<input type="checkbox"/> 3	<input type="checkbox"/> 2	<input type="checkbox"/> 1	<input type="checkbox"/> 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