

## Diabetes Network for Northern Ireland (December 2017)

### Pathway for the Managed Access of FreeStyle Libre<sup>®</sup> (Flash Glucose monitoring) for Adults and Children in the care of Trust Specialist Diabetes Clinics in Northern Ireland

[www.hscboard.hscni.net/download/PUBLICATIONS/pharmacy\\_and\\_medicines\\_management/correspondence/Pathway-for-the-Managed-Access-of-FreeStyle-Libre.docx](http://www.hscboard.hscni.net/download/PUBLICATIONS/pharmacy_and_medicines_management/correspondence/Pathway-for-the-Managed-Access-of-FreeStyle-Libre.docx)

This pathway is for use by secondary care diabetes health care professionals, to assess if patients are suitable for a trial period of the FreeStyle Libre<sup>®</sup> system or for supply of sensors on prescription (for those who have previously been self-funding). It does not cover assessment of patients for continuous glucose monitoring. The pathway provides criteria and additional points for consideration to support clinical decision making processes. The application of the points for consideration will be dependent upon clinical judgement and individual patient circumstances.

Note: The use of FreeStyle Libre<sup>®</sup> in pregnancy is outside the scope of this pathway

#### Criteria for a 3-6 month trial of FreeStyle Libre<sup>®</sup>

(NOTE: These criteria must also be met when establishing if patients who have been self-funding are now eligible for supply of sensors on prescription).

- 1) Type 1 Diabetes.
- 2) Have undergone (or willing to undertake) previous 'advanced insulin self-management education' e.g. DAFNE, BERTIE, CHOICE.

#### Additional clinical points to be considered:

- 3) Utilising effective basal bolus insulin self-management with evidence of CHO counting and correction insulin use with an SMBG frequency of >4 tests daily.
- 4) Problematic BG Control or difficulties maintaining good control, despite the above e.g.
  - a. Variable SMBG control with episodic hypoglycaemia impacting on lifestyle.
  - b. Recurrent hypoglycaemia (> 3 episodes per week or >2 severe episodes in a year).
  - c. Loss of hypoglycaemia Awareness Symptoms ('Modified Clarke and Gold Score' >4; NICE NG17. See Appendix 1).
  - d. Persistent Elevation of HbA1c despite insulin dose adjustments.
  - e. Severe physical, psychological or occupational barriers to effective SMBG.

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5) Substantial evidence of benefit in maintaining good glucose control with a sensor device.

6) Regular attendance at secondary care clinic.

### **Action Pathway** (for patients assessed as suitable for a trial of FreeStyle Libre®)

- Initial assessments.
- Full examination and biochemical assessment of potential confounders of control (e.g. thyroid/adrenal/coeliac assessment).
- SMBG control or Diagnostic (Professional) CGM (iPro or equivalent) as a baseline assessment.

All outcomes of assessments and clinical results should be recorded in the patient's medical notes.

### **Consent and Training**

#### For first time users of FreeStyle Libre®

- Patient consent obtained to ensure that they wish to trial the FreeStyle Libre® system.
- Patient referred to clinic for training.
- Attendance at training confirmed and patient still wishes to proceed.
- Patient supplied with FreeStyle Libre® reader and starter pack of sensors at training clinic.

#### For ALL patients (including those who have previously self-funded FreeStyle Libre®)

- Patients to be informed that they will be reviewed in 3-6 months, to assess if they have met the criteria for ongoing use of FreeStyle Libre®.
- Patient's current method of testing blood glucose and/or blood ketones to be reviewed. Note: The FreeStyle Libre® reader has a built in port to enable blood glucose and ketone testing. This requires use of FreeStyle Optium® blood glucose test strips and FreeStyle Optium β Ketone® strips, which are NOT cost effective choices of blood glucose and ketone strips. (see price lists in appendix 6). Patients should therefore be given separate glucometer(s), which, where possible use cost effective blood glucose strips; <£10 for 50 and cost effective ketone test strips <£10 for 10, to use alongside FreeStyle Libre®.
- Patient provided with patient information leaflet (see sample leaflets; appendix 4 and 5). This should explain the process for review, so that the patients understand, from the outset that prescribing may not continue if criteria are

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not met and also details of what to do if they receive a faulty sensor i.e. contact Abbott Manufacturer;  
Customer Service Telephone number: 0800 1701177 (Mon – Fri 8am -8pm) excluding bank holidays).

### **GP Communication**

Letter to be issued from the training clinic to patients GP. Letter to outline the following: (see sample letters in appendix; 2 and 3).

- Patient has met the criteria for a 3-6 month trial of FreeStyle Libre<sup>®</sup> or is now eligible to receive sensors on prescription, after previously self- funding.
- Patient has received training on the device.
- If the patient is less than 4 years old, GP to be informed that use of FreeStyle Libre<sup>®</sup> is off licence. Clarification obtained from GP that they are willing to undertake prescribing.
- First time users have been supplied with FreeStyle Libre<sup>®</sup> reader and starter pack of sensors
- Request GP to issue prescriptions for FreeStyle Libre<sup>®</sup> sensors (maximum 2 per month).
- Inform GP of the patient's review date for assessment of continued use.
- Inform GP of the name of blood glucose test strips (and ketone strips, if appropriate), which will be used alongside the FreeStyle Libre<sup>®</sup> system.
- Inform GP that they should contact secondary care at any time, if they are concerned as to the appropriateness of the continued use of FreeStyle Libre<sup>®</sup> system for a particular patient.

### **Review criteria**

Ideally 3 monthly assessments (with regular data upload) whilst on trial to confirm:

- 1) Use of each sensor for at least 70% of the time.
- 2) Effect of sensor use on reduction of BG variability and increase of percentage of time spent in target BG range (4-10mmol/L) compared to baseline
- 3) Improvement in the initial problem triggering the trial.

If all 3 criteria are achieved, then approve continued use of sensors (reviewed annually) with expectation of ongoing regular contact and sensor upload by diabetes specialist team.

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If use is suboptimal or does not result in effective change then sensor supply withdrawn and alternative avenues for the assistance of the individual are assessed.

4) Patient's GP to be informed by letter of outcome of the review. Advised to cease or continue prescribing of FreeStyle Libre<sup>®</sup> sensors.

### **Specialist Clinic Reporting to Diabetes Network Technology sub group**

- 1) Quarterly report of numbers of patients assessed by GP practice
- 2) Quarterly report of numbers of patients offered a 3-6 month trials.
- 3) Quarterly report of numbers of trial successful and numbers of established users continuing effective use (after year 1).

### **Audit**

Trusts will undertake to carry out regular audits to ensure that the pathway has been appropriately applied, with results reported to the Technology Subgroup. Initial audit to be undertaken after 6 months and annually thereafter.

### **Review**

This pathway will be reviewed as further clinical evidence for FreeStyle Libre<sup>®</sup> becomes available or guidance is issued by NICE.

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## Appendix 1: Clarke Hypoglycaemic Index Score

1. Pick the category that best describes you: (pick only one)

<input type="checkbox"/>	I always have symptoms when my blood sugar is low	0	total
<input type="checkbox"/>	I sometimes have symptoms when my blood sugar is low	1	
<input type="checkbox"/>	I no longer have symptoms when my blood sugar is low		

2. Have you lost some of the symptoms that used to occur when your blood sugar was low?

<input type="checkbox"/>	Yes	1	total
<input type="checkbox"/>	No	0	

3. In the past 6 months how often have you had moderate hypoglycemia episodes? (Episodes where you might feel confused, disoriented, or lethargic and were unable to treat yourself)

<input type="checkbox"/>	Never	0	total
<input type="checkbox"/>	once or twice in 6 months	1	
<input type="checkbox"/>	once a month		
<input type="checkbox"/>	every other month		
<input type="checkbox"/>	more than once a month		

4. In the past year how often have you had severe hypoglycemia episodes? (Episodes where you were unconscious or had a seizure and needed glucagon or intravenous glucose)

<input type="checkbox"/>	Never	0	total
<input type="checkbox"/>	1 time	1	
<input type="checkbox"/>	3 times		
<input type="checkbox"/>	2 times		
<input type="checkbox"/>	≥4 times		

5. How often in the last month have you had readings < 3.5mmol/L **with** symptoms?

<input type="checkbox"/>	never	<input type="checkbox"/>	1 time/week	<input type="checkbox"/>	4 to 5 times/week
<input type="checkbox"/>	1 to 3 times	<input type="checkbox"/>	2 to 3 times/week	<input type="checkbox"/>	almost daily

6. How often in the last month have you had readings < 3.5 mmol/l **without** symptoms?

<input type="checkbox"/>	never	<input type="checkbox"/>	1 time/week	<input type="checkbox"/>	4 to 5 times/week
<input type="checkbox"/>	1 to 3 times	<input type="checkbox"/>	2 to 3 times/week	<input type="checkbox"/>	almost daily

7. How low does your blood sugar need to go before you feel symptoms?

<input type="checkbox"/>	3.4-3.9	0	total
<input type="checkbox"/>	2.8-3.3	1	
<input type="checkbox"/>	2.2-2.7		
<input type="checkbox"/>	<2.2		

8. To what extent can you tell by your symptoms that your blood sugar is low?

<input type="checkbox"/>	Always	0	total
<input type="checkbox"/>	often	1	
<input type="checkbox"/>	rarely		
<input type="checkbox"/>	sometimes		
<input type="checkbox"/>	never		

Score 1 if reading <3.5 with no symptoms

Total =

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### **Appendix 2:** Sample letter to send to GP for first time users of FreeStyle Libre® (following patient's attendance at training clinic)

Dear Dr {insert name},

Your patient, {insert name} has been assessed in line with regional guidance, as eligible for a trial of the flash glucose monitoring System, FreeStyle Libre®. {Insert name} has attended a training clinic on {insert date}.

We have supplied the patient with a FreeStyle Libre® reader and starter pack of sensors. We would be grateful if you could continue the prescribing of FreeStyle Libre® sensors on a monthly basis for the patient.

Each sensor lasts for 14 days, so a supply of 2 sensors per month is necessary.

Patients have been advised that should they receive a 'faulty' sensor, they should NOT request additional supplies via prescription but contact the company to obtain a replacement. (Abbott UK General Customer Service telephone number is 0800 1701177. It is open from 8am to 8pm, Monday to Friday; excluding bank holidays).

{Insert name} will be reviewed on {insert date} to assess if they have met the criteria to continue long term use of the FreeStyle Libre® system. We will write to you, following this review, to inform you of the outcome. In some cases ongoing prescribing of FreeStyle Libre® sensors will not be required. If, at any time, you are concerned about the appropriateness of the use of FreeStyle Libre® for your patient, please feel free to contact us directly.

Patients will still, on occasions (e.g. to meet DVLA requirements, during periods of sickness) be required to perform blood glucose {\*delete as appropriate *and/or ketone blood*} testing. Please prescribe {insert name of blood glucose test strip and/or ketone test strips} for use alongside the FreeStyle Libre® system.

Yours sincerely,

{Insert prescriber's name}

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### Appendix 3: Sample letter to send to GP for patients who have already been using the FreeStyle Libre<sup>®</sup> system.

Dear Dr {insert name},

Your patient, {insert name} has been self- funding the FreeStyle Libre<sup>®</sup> system and has been assessed in line with regional guidance, as now being eligible to obtain FreeStyle Libre<sup>®</sup> sensors on prescription.

The patient has their own FreeStyle Libre<sup>®</sup> reader. We would be grateful if you could prescribe FreeStyle Libre<sup>®</sup> sensors on a monthly basis for the patient.

Each sensor lasts for 14 days, so a supply of 2 sensors per month is necessary.

Patients have been advised, that should they should receive a 'faulty' sensor, they should NOT request additional supplies via prescription but contact the company to obtain a replacement. (Abbott UK General Customer Service telephone number is 0800 1701177. It is open from 8am to 8pm, Monday to Friday; excluding bank holidays).

{Insert name} will be reviewed on {insert date} to assess if they continue to meet the criteria for ongoing long term use of the FreeStyle Libre<sup>®</sup> system. We will write to you, following this review, to inform you of the outcome. In some cases ongoing prescribing of FreeStyle Libre<sup>®</sup> sensors will not be required. If at any time you are concerned about the appropriateness of the use of FreeStyle Libre<sup>®</sup> for your patient, please feel free to contact us directly.

Patients will still, on occasions (e.g. to meet DVLA requirements, during periods of sickness) be required to perform blood glucose {\*delete as appropriate *and/or ketone blood*} testing. Please prescribe {insert name of blood glucose test strip and/or ketone test strips} for use alongside the FreeStyle Libre<sup>®</sup> system.

Yours sincerely,

{Insert prescriber's name}



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### **Appendix 4:** Sample Patient Information Leaflet FreeStyle Libre®

(for first time users)

Following assessment by your specialist diabetes team, you have been assessed as being eligible for a trial of FreeStyle Libre® system.

You will have received the appropriate training on the system and have been provided with a FreeStyle Libre® reader and starter pack of sensors.

We have written to your GP to request that they prescribe a maximum of 2 FreeStyle Libre® sensors per month for you.

Please note that should you receive a 'faulty sensor', DO NOT contact your GP for another prescription. Please contact the manufacturer (Abbott) directly for a replacement.

Abbott Customer Service Telephone number: 0800 1701177 (Mon – Fri 8am -8pm) excluding bank holidays).

You will be reviewed at your next hospital appointment (usually in 3-6 months) where you will be assessed to check that you have met criteria to continue the prescribing of FreeStyle Libre® sensors on prescription.

If you meet the review criteria, prescribing of the sensors will continue and you will be reviewed on annual basis, to assess if FreeStyle Libre® is still beneficial to help to manage your diabetes.

In cases where the review criteria are not met, it may be necessary for your diabetes specialist to write to your GP to request that prescribing of the sensors is no longer appropriate. Your diabetes specialist will discuss with you other available options, to help manage your diabetes.

You will have been made aware at your FreeStyle Libre® training session that a finger-prick test using a glucometer is still required e.g. during times of rapidly changing glucose levels (i.e. acute illness), if hypoglycaemia (low blood sugars) or impending hypoglycaemia is reported, or the symptoms do not match the system readings and also prior to, and during driving, to meet current DVLA requirements.

Your diabetes specialist will discuss with you the most suitable glucometer for you to use alongside your FreeStyle Libre® system.

If you have any queries, please feel free to contact {insert name} for further information.

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### Appendix 5: Sample Patient Information Leaflet FreeStyle Libre®

(for patients who have previously self-funded)

Following assessment by your specialist diabetes team, you have been assessed as being eligible to receive FreeStyle Libre® sensors on prescription.

We have written to your GP to request that they prescribe a maximum of 2 FreeStyle Libre® sensors per month for you.

Please note that should you receive a 'faulty sensor', DO NOT contact your GP for another prescription. Please contact the manufacturer (Abbott) directly for a replacement.

Abbott Customer Service Telephone number: 0800 1701177 (Mon – Fri 8am -8pm) excluding bank holidays).

You will be reviewed at your next hospital appointment (usually in 3-6 months) where you will be assessed to check that you have met criteria to continue the prescribing of FreeStyle Libre® sensors on prescription.

If you meet the review criteria, prescribing of the sensors will continue and you will be reviewed on annual basis, to assess if FreeStyle Libre® is still beneficial to help to manage your diabetes.

In cases where the review criteria are not met, it may be necessary for your diabetes specialist to write to your GP to request that prescribing of the sensors is no longer appropriate. Your diabetes specialist will discuss with you other available options, to help manage your diabetes.

You will be aware when using the FreeStyle Libre® system, that a finger-prick test using a glucometer is still required e.g. during times of rapidly changing glucose levels (i.e. acute illness), if hypoglycaemia (low blood sugars) or impending hypoglycaemia is reported, or the symptoms do not match the system readings and also prior to, and during driving, to meet current DVLA requirements.

Your diabetes specialist will discuss with you the most suitable glucometer for you to use alongside your FreeStyle Libre® system.

If you have any queries, please feel free to contact {insert name} for further information.