# Protocol for initiating FreeStyle Libre® for glucose monitoring

# In CHILDREN

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)
- 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 paediatric patients (over the age of four) with Type 1 diabetes, according to the patient selection criteria below (see separate guidance for adults) 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 three months of use
- 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. 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 at one month and 3 months of use and is assessed on their use of FreeStyle Libre®. The FreeStyle Libre® sensors must be supplied by the specialist team for at least the first 3 months of use pending further review (one month supply on first initiation, followed by two month supply). This will be followed by a review with the specialist team at 3 months.
- 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.
- If a patient does not meet the outcomes then the specialist will stop the FreeStyle Libre® device and will notify the GP of this using the proforma in Appendix B
- 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 Responsibilities

- Patient has been assessed by the specialist team and is deemed to be suitable for initiation of FreeStyle Libre®.
- Specialist has written to the GP using the proforma in Appendix A detailing the reasons why FreeStyle Libre® has been initiated.
- GP to continue prescribing FreeStyle Libre® sensors in primary care.
- Patient will be reviewed by the specialist team regularly.
- GP will stop prescribing FreeStyle Libre® if notified by the specialist team (Appendix B).
- GP to prescribe replacement sharps bins, as required, for the disposal of sensors (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 (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®
- 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 at least 8 times a day and will use the sensor > 70% of the time.

## Patient Selection: Children and young people (<19 years of age)

Paediatric patients who meet the criteria outlined within the national guideline developed by the Association of Children's Diabetes Clinicians (ACDC) will be eligible for Continuous Glucose monitoring (CGM)/FreeStyle Libre® on the NHS. The Executive summary can be found at; http://www.a-c-d-c.org/wp-content/uploads/2012/08/CGM-FGS-Executive-Summary-April-2017.pdf For the purpose of this document, the criteria relate to the use of FreeStyle Libre®.

- FreeStyle Libre® may be initiated in patients with any form of diabetes who require haemodialysis and use insulin; it is also suitable for diabetes associated with cystic fibrosis where insulin is required.
- FreeStyle Libre® can be considered for children on insulin pump therapy or multiple daily injections.
- FreeStyle Libre® can be considered for improving diabetes control in children and young people by reducing HbA1c and/or reducing the time spent in hypoglycaemia, in patients with any HbA1c <85 mmol/mol (>85mmol/mol is an indication that insulin is not being used regularly)
- FreeStyle Libre® may be used where fear of hypoglycaemia provokes clinically significant anxiety and is a barrier to good control.
- In patients with frequent hypoglycaemia or nocturnal hypoglycaemia, NICE advise the use of a continuous glucose monitoring system with an in-built alarm function. At present, the FreeStyle Libre® does not have an alarm.
- The FreeStyle Libre® may be considered in certain circumstances where capillary blood glucose monitoring within the school or nursery environment is challenging and adversely affecting control (note – training will be given to the school by the specialist team).
- FreeStyle Libre® could be considered for exercise in children and young people 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 adolescents 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

- Where clinically appropriate FreeStyle Libre® may be considered in patients doing more than 6 capillary blood tests daily as likely to be cost neutral.
- In pregnancy, FreeStyle Libre® may be used for a period of 12 months (including the post delivery period) as hypoglycaemia awareness is reduced in pregnancy. GPs should refer all patients in this group to the specialist team as soon as possible.

In order to maximise benefit patients must use the device at least 70% of the time (5/6 days a week minimum). Ideally it should be used continuously.

All patients will have a defined trial period of the FreeStyle Libre®. Attendance at specific teaching/training sessions is a key pre-requisite of NHS provision of FreeStyle Libre® systems. Primary care will be asked to prescribe after training has been received and the trial period completed. The specialist will continue to monitor effectiveness and advise the GP on continued need.

## Criteria for stopping in children and young people

FreeStyle Libre® will be withdrawn in patients where:
**After 1 month** of use the following has not been achieved:

- The device has not been used 70% of the time – 5/6 days a week minimum
- The family have not attended training sessions on the use of the device

**After 3 months** of use the following has not been achieved:

- Not worn for at least 5 days a week
- No improvement in any of the following:
    - No improvement in scores on fear of hypoglycaemia scales where device was introduced for anxiety
    - No reduction in frequency of hypoglycaemia
- If HbA1c has not improved by >0.5% for patients whose starting HbA1c was >7.5% (58 mmol/mol) then the specialist **could** consider withdrawing the device.

***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**

## Children and young people

### 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 has any form of diabetes and on haemodialysis and using insulin | |
| Patient has diabetes associated with cystic fibrosis where insulin is required. | |
| Improve diabetes control in children and young people by reducing HbA1c in patients with any HbA1c <85mmol/mol | |
| Patient undertakes intensive monitoring >6 times daily | |
| Planning pregnancy or pregnant | |
| Fear of hypoglycaemia provokes clinical significant anxiety | |
| Capillary blood glucose monitoring within the school or nursery environment is challenging and is adversely affecting control | |
| Exercise in children and young people in the following circumstances:<br>• 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.<br>• For adolescents 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<br>• For those in whom there is concern regarding overcompensation with additional carbohydrate for activity<br>• Those involved in high endurance sporting activities where it is difficult to test blood sugar<br>• For those where exercise results in unpredictable hypoglycaemia | |

## Outcomes Monitoring

The following outcomes will be monitored by the specialist team at each review.

| **Parameter** | **Comments** |
|---|---|
| Frequency of severe/non-severe hypoglycaemia | |
| Improvement in scores on fear of hypoglycaemia scales (if device used for anxiety)? | |
| Has the patient worn the device for at least 5 days a week? | |
| Has the patient used FreeStyle Libre in an appropriate way? I.e. Commitment to training and education, to regular scans and their use in self-management | |
| HbA1c level<br>If HbA1c has not improved by >0.5% for patients whose starting HbA1c was >7.5% (58.0mmol/mol) the specialist could **consider** withdrawing the device | |

**APPENDIX B**

## Children and young people

### Proforma for notifying GP of withdrawal of FreeStyle Libre® device

- Specialist to complete when notifying GP of withdrawal of FreeStyle Libre®.
- Both parties should retain a copy of the form in the patient's record.

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

### Patient details

Name: _____ ID Number: _____

Address: _____ DOB: _____

### Withdrawal of FreeStyle Libre®

As a result of the above patient not achieving the desired outcome(s) stated below, the decision has been made to withdraw the FreeStyle Libre® device and for the patient to revert to monitoring as previously.

| **Outcome** | **Comments** |
|---|---|
| No improvement in the frequency of severe/non-severe hypoglycaemia. | |
| No improvement in scores on fear of hypoglycaemia scales (if device used for anxiety). | |
| Patient is not committed to using FreeStyle Libre® in an appropriate way. For example:<br>o Not worn the device for at least 5 days a week?<br>o No commitment to training and education<br>o Not scanning regularly | |
| No improvement in HbA1c | |
| Other reason (please specify) | |