Protocol for initiating FreeStyle Libre® 2 for glucose monitoring

In CHILDREN

FreeStyle Libre®/FreeStyle Libre 2® 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.

FreeStyle Libre 2® was launched in November 2020. Freestyle Libre 2® has the added benefit of 3 optional real-time alarms (low glucose alarm, high glucose alarm, signal loss alarm).[1] All new patients will be initiated on FreeStyle Libre 2® and existing patients will be transferred to FreeStyle Libre 2® by the specialist team (FreeStyle Libre® will remain available if the patient does not wish to switch over to FreeStyle Libre 2®).

FreeStyle Libre 2® **sensors are not interchangeable** with FreeStyle Libre® sensors and require a different reader or the FreeStyle LibreLink app to scan and receive the results.[2] The patient can order a replacement reader via the FreeStyle Libre website: FreeStyleLibre.co.uk/replacement (FreeStyle Libre 2® sensors can be used with the original reader, but there will be no alarm function, and therefore it is recommended to obtain the FreeStyle Libre 2® reader or use the FreeStyle LibreLink app as soon as possible)

With FreeStyle Libre 2® patients choose which device they want to receive alarms on: FreeStyle Libre 2® reader or FreeStyle LibreLink app. They must start their FreeStyle Libre 2® sensor with that selected device. Once the patient scans their FreeStyle Libre 2® sensor with that device, they can receive alarms only on that device.[1]

Use of FreeStyle Libre®/FreeStyle Libre 2® should reduce the frequency of finger prick monitoring to measure blood glucose levels.

However with the first generation FreeStyle Libre® system, 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

Because of the excellent accuracy of the FreeStyle Libre 2® system, there is no need to use blood glucose testing, even when glucose is low, falling or rapildly changing.[1] However blood glucose levels should still be taken to meet DVLA requirements (https://www.gov.uk/diabetes-driving) or if scanned glucose readings and alarms do not match symptoms or expectations.

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®/FreeStyle Libre 2® 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 2®:

- FreeStyle Libre 2® 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; or for patients with Type 1 diabetes or insulin treated Type 2 diabetes who are living with a learning disability and recorded on their GP Learning Disability register.[3]
- FreeStyle Libre 2® 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 2®.
- Patient/patient's carer is educated on the use of FreeStyle Libre 2® 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 2®. The FreeStyle Libre 2® 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®/FreeStyle Libre 2® 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
- **Transfer of patient from FreeStyle Libre® to FreeStyle Libre 2®:** the specialist will send the proforma in **Appendix C** to the patient's GP to request that the patient is transferred to FreeStyle Libre 2®. Patient/patient's carer is educated by the specialist team (either by telephone, online or in person) on the use of FreeStyle Libre 2® and the requirement to order a new reader or use the FreeStyle LibreLink app. The specialist will also advise the patient to use up current stock of FreeStyle Libre® sensors where appropriate before starting to use FreeStyle Libre 2®. Providing the patient has been using FreeStyle Libre® for at least 3 months, the GP will be responsible for prescribing the FreeStyle Libre 2® sensors.

GP Responsibilities

- Patient has been assessed by the specialist team and is deemed to be suitable for initiation of FreeStyle Libre 2®.
- Specialist has written to the GP using the proforma in **Appendix A** detailing the reasons why FreeStyle Libre 2® has been initiated.
- GP to continue prescribing FreeStyle Libre 2® sensors in primary care.
- Patient will be reviewed by the specialist team regularly.
- GP will stop prescribing FreeStyle Libre®/FreeStyle Libre 2® 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).
- **Transfer of patient from FreeStyle Libre® to FreeStyle Libre 2®:** GP/Clinical Pharmacist to prescribe FreeStyle Libre 2® sensors at the request of the specialist team (using the proforma in **Appendix C**), providing the patient has been educated on the use of FreeStyle Libre 2® by the specialist team and has been using FreeStyle Libre® for at least 3 months.

Patient Responsibilities

- Patient/patient's carer will undergo training on the use of FreeStyle Libre 2®
- Patient will commit to ongoing regular follow-up and monitoring with the specialist diabetes team and will be committed to using the FreeStyle Libre 2® device.
- The FreeStyle Libre 2® 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)/ Flash Glucose Scanning (FreeStyle Libre®/FreeStyle Libre 2®) on the NHS. The Executive summary (October 2019) can be found at; http://www.a-c-d-c.org/wp-content/uploads/2012/08/Executive-Summary-A-Practical-Approach-to-the-Management-of-Continuous-Glucose-Monitoring-CGM-Real-Time-Flash-Glucose-Scanning-FGS-in-Type-1-Diabetes-Mellitus-in-Children-and-Young-People.pdf

Also note the NHS England Flash Glucose Monitoring: National arrangements for funding of relevant diabetes patients **(**updated November 2020).[3]

For the purpose of this document, the criteria relate to the use of FreeStyle Libre 2®.

- FreeStyle Libre 2® 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 2® may be initiated in patients with Type 1 diabetes or insulin treated Type 2 diabetes who are living with a learning disability and recorded on their GP Learning Disability register.[3]
- FreeStyle Libre 2® can be considered for children on insulin pump therapy or multiple daily injections.
- FreeStyle Libre 2® 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 2® may be used where fear of hypoglycaemia provokes clinically significant anxiety and is a barrier to good control.
- For those with Type 1 diabetes and recurrent severe hypoglycemia or impaired awareness of hypoglycemia, NICE suggests that Continuous Glucose Monitoring with an alarm is the standard. Other evidence-based alternatives with NICE guidance or NICE TA support are pump therapy, psychological support, structured education, islet transplantation and whole pancreas transplantation. However, if the person with diabetes and their clinician consider that a Flash Glucose Monitoring system would be more appropriate for the individual's specific situation, then this can be considered.[3]

Note that the first generation FreeStyle Libre® does not have an alarm function. FreeStyle Libre 2® has optional real-time alarms but it cannot connect directly to insulin pumps to suspend insulin administration.

- FreeStyle Libre 2® 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 2® 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 2® may be considered in patients doing more than 6 capillary blood tests daily as likely to be cost neutral.
- In pregnancy, FreeStyle Libre 2® 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 2®. Attendance at specific teaching/training sessions is a key pre-requisite of NHS provision of FreeStyle Libre 2® 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®/FreeStyle Libre 2® 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.

References

1. The FreeStyle Libre 2 system for healthcare professionals. Available at: https://freestylediabetes.co.uk/health-care-professionals/freestyle-libre/freestyle-libre-system Accessed <10.03.21>
2. PSNC Newly launched FreeStyle Libre 2 Sensors enter the Drug Tariff and DND list from November 2020 Available at: https://psnc.org.uk/our-news/freestyle-libre-2-sensors-added-to-drug-tariff-and-dnd-list-from-november-1st-2020/#:~:text=FreeStyle%20Libre%202%20Sensors%20are%20not%20interchangeable%20with,via%20the%20Abbott%20Diabetes%20Care%20pharmacy%20ordering%20portal. Accessed <10.3.21>
3. NHS England Flash Glucose Monitoring: National arrangements for funding of relevant diabetes patients. Updated November 2020. Available at: https://www.england.nhs.uk/publication/flash-glucose-monitoring-national-arrangements-for-funding-of-relevant-diabetes-patients/ Accessed <10.3.21>

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 12th May 2021.*

APPENDIX A

Children and young people

Proforma for transfer of prescribing of FreeStyle Libre 2® to primary care

- Specialist to complete when requesting GP to take over prescribing of FreeStyle Libre 2®.
- GP to return signed copy of form to barnsleydiabetes.spa@nhs.net
- 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.	
Patients with Type 1 diabetes or insulin treated Type 2 diabetes who are living with a learning disability and recorded on their GP Learning Disability register.	
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: • 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 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	

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 2® in an appropriate way? I.e. Commitment to training and education, to regular scans and their use in self-management	
HbA1c level 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	

Confirmation of acceptance from GP

The patient has met the criteria for the initIation of FreeStyle Libre 2® 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 Libre2® for the patient named above.
- □ Reject the request to prescribe FreeStyle LIbre2® for the patient named above. The reason for this being ……..

APPENDIX B

Children and young people

Proforma for notifying GP of withdrawal of FreeStyle Libre®/FreeStyle Libre 2® device

- Specialist to complete when notifying GP of withdrawal of FreeStyle Libre®/FreeStyle Libre 2®.
- 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®/FreeStyle Libre 2®

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®/FreeStyle Libre 2® 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®/FreeStyle Libre 2® in an appropriate way. For example: o Not worn the device for at least 5 days a week? o No commitment to training and education o Not scanning regularly	
No improvement in HbA1c	
Other reason (please specify)	

APPENDIX C

Children and young people

Proforma for transfer of patient from FreeStyle Libre® to FreeStyle Libre 2®

- Specialist to complete when requesting GP to transfer patient from FreeStyle Libre® sensors to FreeStyle Libre 2® sensors.

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

Patient details

Name: _____ ID Number: _____

Address: _____ DOB: _____

Request to prescribe Freestyle Libre 2® sensors

Please can you prescribe Freestyle Libre 2® sensors as a replacement for FreeStyle Libre® sensors for the above patient.

I can confirm that:

- the patient/patient's carer has been educated by the specialist team (either by telephone, online or in person) on the use of FreeStyle Libre 2® and the requirement to order a new reader or use the FreeStyle LibreLink app.
- the patient has been using FreeStyle Libre® for at least 3 months and prescribing of FreeStyle Libre has previously been transferred to primary care using the proforma for transfer of prescribing of FreeStyle Libre® to primary care**.**

Specialist name: _____ Telephone number(s): _____

Specialist signature: _____ Date: _____