

Protocol for initiating FreeStyle Libre 2® for glucose monitoring

In ADULTS

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](https://www.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)
- 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

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 rapidly 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 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; 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 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 2®.
- Patient/patient's carer is educated (either online or in person) 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 regularly for the first 3 months of use (at least 3 monthly) and is assessed on their use of FreeStyle Libre 2®. A full record of the review is made and is communicated to primary care (including information relating to outcomes). The FreeStyle Libre 2® 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.
- **Transfer of patient from FreeStyle Libre® to FreeStyle Libre 2®:** the specialist will send the proforma in **Appendix B** 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/Clinical Pharmacist Responsibilities

- Patient has been assessed by the specialist team and is deemed to be suitable for initiation of FreeStyle Libre 2®.
- Patient has been using FreeStyle Libre 2® 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 2® has been initiated and the improvement in outcomes that has been achieved.
- GP/Clinical Pharmacist to continue prescribing FreeStyle Libre 2® 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>.
- **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 B**), 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®.
- 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 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 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 2® 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 C**).
- 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 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).
- Patients with diabetes associated with cystic fibrosis requiring insulin therapy.
- 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

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 2® 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 2® 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

- 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.
- 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 C**)
- Patient is not engaging with the specialist team on a regular basis

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%20%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**ADULTS****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 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 | |
| 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. | |
| 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 | |
| <p>Exercise in adults in the following circumstances:</p> <ul style="list-style-type: none"> • 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 | | | |
| <p>HbA1c level</p> <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 2® 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 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

ADULTS

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: _____

APPENDIX C

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

The nine processes of care:

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