





# Protocol for initiating FreeStyle Libre® 2+ for glucose monitoring in CHILDREN 18 years and under

**FreeStyle Libre® 2+** is a Real Time Continuous Glucose Monitoring (CGM) system (and flash CGM if the sensor is started with the reader) 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.



#### Blood Glucose Monitoring

Measures the glucose levels in capillary blood vessels.

- A lancet is inserted to reach the blood in the capillary.
- A finger prick only provides one measurement at one point in time.
- Requires a whole kit, including lancets and a blood glucose reader.

#### The FreeStyle Libre 2 system

Continuously measures the glucose levels in interstitial fluid (ISF): the fluid between the cells under the skin.

- Glucose readings based on interstitial fluid have been shown to reliably reflect glucose levels.
- The sensor is painless to apply and use.
- The sensor takes a glucose reading every minute.
- · Monitor your glucose on the go with zero finger pricks.

FreeStyle Libre® 2+ was launched in March 2024. Freestyle Libre® 2+ has the 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® 2 has been discontinued and is no longer available to prescribe).<sup>1,6</sup>

FreeStyle Libre® 2+ sensors use either the FreeStyle LibreLink app to receive the results continuously every 1 minute to your smartphone or the libre 2 reader to scan the sensor to receive the readings on your smartphone and Libre 2 reader. FreeStyle Libre® 2+ sensors can be used with the Libre 2 reader, however, use of the Libre FreeStyle LibreLink app allows for real time readings every 1 minute and the sharing of readings with family and friends.

NOTE: If you start your FreeStyle Libre® 2+ sensor with your FreeStyle Libre 2 reader <u>you will not receive real time continuous glucose readings</u>, even if you use the updated FreeStyle LibreLink app as your second device. You will need to flash scan your sensor to get your glucose reading on both devices. Glucose alarms are only received on the device used to start the sensor. Sensor expires dates and times are only available on the device used to start the sensor.

Before trying to initiate your readings onto the app you will need to check that your smartphone make and model are compatible with the LibreLink App. To do this please visit:

https://www.diabetescare.abbott/support/manuals/uk.html.(Please note you may be able to download the app but if your smartphone is not compatible you will be unable to obtain CGM readings on your smartphone).

Use of FreeStyle Libre® 2+ sensor should reduce the frequency of finger prick monitoring to measure blood glucose levels¹. Because of the accuracy of the FreeStyle Libre® 2+ system, there is no need to use finger-prick testing when glucose is low, falling or rapidly changing.¹ However, blood glucose levels should still be taken to meet DVLA³ requirements or if scanned glucose readings and alarms do not match symptoms or expectations.¹ In line with DVLA requirements³, continuous glucose monitoring may be used for Group 1 drivers at times relevant to driving providing a finger-prick test is used to confirm readings:

- When glucose levels are 4.0 mmol/litre or below.
- When symptoms of hyperglycaemia are being experienced; or
- When FreeStyle Libre® 2+ gives a reading which is inconsistent with the symptoms being experienced. (that is, you have symptoms of hypoglycaemia and your system reading does not indicate this).
- If you are aware that you have become hypoglycaemic or have indication of impending hypoglycaemia. At any other times recommended by the manufacturer of your glucose monitoring system.
- Alarms on RT-CGM devices must not be used as a substitute for symptomatic awareness of hypoglycaemia. You must recognise hypoglycaemia through the symptoms you experience for the purposes of Group 1 driving. Should you become reliant on these alarms to advise you that you are hypoglycaemic you must stop driving and notify the DVLA.

If you are using a glucose monitoring system (CGM or FGM) you must not actively use this whilst driving your vehicle. You must pull over in a safe location before checking your device. You must stay in full control of your vehicle at all times. The police can stop you if they think you're not in control because you're distracted and you can be prosecuted.

FreeStyle Libre<sup>®</sup> 2+ (and any other form of interstitial glucose monitoring) is not permitted for Group 2 drivers who must continue to follow the DVLA guidelines on capillary finger-prick testing to maintain their licenses. Group 2 drivers may still benefit from FreeStyle Libre<sup>®</sup> 2+ but will need to use capillary monitoring even on days where they are not planning to drive<sup>3</sup>.

Blood testing strips should be prescribed according to locally agreed best value guidelines with an expectation that demand/frequency of supply will be reduced.<sup>4</sup>

#### Initiation and supply of Freestyle Libre® 2+ in Barnsley Place:

FreeStyle Libre<sup>®</sup> 2+ can only be initiated in paediatric patients (over the age of two years) by the diabetes specialist team in the following patients:

- Children with Type 1 diabetes
- Children with any form of diabetes receiving haemodialysis and requiring insulin therapy
- Children with diabetes associated with cystic fibrosis requiring insulin therapy;
- Children with insulin treated Type 2 diabetes who have a condition or disability (including cognitive impairment) which means that they cannot self-monitor blood glucose using capillary testing but could use FreeStyle Libre® 2+ or have it scanned for them.
- Children with type 2 diabetes who would otherwise be advised to self-measure at least 8 times a day.
- Children with type 2 diabetes who have recurrent or severe low blood sugar levels.
- Children with type 2 diabetes who are pregnant may be offered a CGM if:
  - they have problematic severe hypoglycaemia (with or without impaired awareness of hypoglycaemia).
  - They have unstable blood glucose levels that are causing concern despite efforts to optimise glycaemic control.
- 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,
  - o An improvement in the required outcomes has been achieved.
- Where continuous glucose monitoring is unsuitable despite education and support, patients must be offered either a capillary glucose monitoring or, where applicable, a Freestyle Libre 2 reader to use as a flash monitor.<sup>4</sup>

#### **Roles and Responsibilities**

#### **Specialist Responsibilities**

- Patient is assessed and is deemed to be suitable for initiation of FreeStyle Libre<sup>®</sup> 2+
- Patient/patient's carer is educated on the use of FreeStyle Libre<sup>®</sup> 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.
- 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® 2+ device and will notify the GP of this.
- 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 four times a year
  and their HbA1c and weight recorded.
- The specialist team will counsel the patient on circumstances where capillary blood glucose monitoring is required in addition to Continuous Glucose monitoring and will clarify that capillary monitoring is not routinely required except in these circumstances.
- Transfer of patient from FreeStyle Libre® 2 to FreeStyle Libre® 2+ may be undertaken in primary care. Primary care should advise the patient to use up current stock of FreeStyle Libre® 2 sensors where appropriate before starting to use FreeStyle Libre® 2+. Patient should be counselled on the fact the sensor lasts 15 days (not 14 as with FreeStyle Libre® 2 and 3). Providing the patient has been using FreeStyle Libre® 2 for at least 3 months, the GP will be responsible for prescribing the FreeStyle Libre® 2+ sensors. From January 2025 all patients should be transferred promptly to FreeStyle Libre® 2+ as FreeStyle Libre® 2 sensors are discontinued.

#### **GP Responsibilities**

- Patient has been assessed by the specialist team and is deemed to be suitable for initiation of FreeStyle Libre<sup>®</sup> 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<sup>®</sup> 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 information
  regarding disposal of sharps bins.
- Transfer of patient from FreeStyle Libre<sup>®</sup> 2 to FreeStyle Libre<sup>®</sup> 2+: GP/Clinical Pharmacist to prescribe FreeStyle Libre<sup>®</sup> 2+ sensors
- Each FreeStyle Libre® 2+ sensor lasts for **15 days** (rather than 14 days for Libre 2). GP practices will need to be aware of this when prescribing for patients and review yearly to ensure appropriate prescribing of max 24 sensors per year.
- **Appendix C**, providing the patient has been educated on the use of FreeStyle Libre<sup>®</sup> 2+ by the specialist team and has been using FreeStyle Libre<sup>®</sup> 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.
- FreeStyle Libre<sup>®</sup> 2+ will no longer be prescribed if. the patient becomes disengaged with use of the device, the device is not being worn regularly or patient prefers capillary blood testing.
- Retain sensor packaging until the sensor has been applied and expired. Batch numbers
  and other information from the packaging will be required by Abbott if a claim for a faulty
  sensor is made.
- Patient will contact Abbott, the manufacturer, to report a faulty sensor (sensor falling off, error message whilst scanning, not connecting to App/reader etc.) either by filling in the form online at <u>Freestyle Libre Abbott sensor report form</u> or by calling 0800 170 1177

#### Criteria for stopping in children and young people

FreeStyle Libre® 2+ may be withdrawn in patients where:

- The patient no longer wishes to use the Freestyle Libre<sup>®</sup> 2+
- The Freestyle Libre® 2+ is not being worn correctly or for long enough periods of time.
- The patient/carer is unable to use the Freestyle Libre® 2+ correctly even with sufficient training.

Withdrawal of Freestyle Libre® 2+ should only be considered after a discussion with the paediatric diabetes team.

#### References

- 1. The FreeStyle Libre® 2+ system for healthcare professionals. Available at: <a href="https://freestylediabetes.co.uk/health-care-professionals/freestyle-libre/freestyle-libre-system">https://freestylediabetes.co.uk/health-care-professionals/freestyle-libre/freestyle-libre-system</a> Last accessed on 28/12/2023.
- 2. Freestyle Libre® Order a replacement sensor, available online at <a href="https://www.freestylelibre.co.uk/libre/fsl2Replacement.html">https://www.freestylelibre.co.uk/libre/fsl2Replacement.html</a>. Last accessed on 28/10/2025.
- 3. DVLA: Assessing fitness to drive: a guide for medical professional, Chapter 3 (Diabetes). Published May 2024. Available online at <a href="https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment\_data/file/1084397/assessing-fitness-to-drive-may-2022.pdf">https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment\_data/file/1084397/assessing-fitness-to-drive-may-2022.pdf</a>) Last accessed on 28/02/2025.
- NICE NG18: Diabetes (Type 1 and Type 2) in children and young people: diagnosis and management. Published 01/08/2015, last updated 29/06/2022. Available online at <a href="https://www.nice.org.uk/guidance/ng18/chapter/Recommendations#type-1-diabetes">https://www.nice.org.uk/guidance/ng18/chapter/Recommendations#type-1-diabetes</a> Last accessed on 28/02/2025.
- 5. NHS England Glucose monitoring for patients living with diabetes. Available at <a href="https://www.england.nhs.uk/diabetes/digital-innovations-to-support-diabetes-outcomes/flash-glucose-monitoring/">https://www.england.nhs.uk/diabetes/digital-innovations-to-support-diabetes-outcomes/flash-glucose-monitoring/</a> Last accessed on 28/02/2025
- 6. NHS BSA: NHS Electronic Drug Tariff February 2025. Available online at Last accessed on 28/02/2025.
- 7. NICE NG3: Diabetes in Pregnancy: Management from Pre-conception to the Post-Natal Period. Published 25/2/2015, last updated 16/12/2020.

  Available online at https://www.nice.org.uk/guidance/ng3 Last accessed on 28/0220235

**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 9<sup>th</sup> April 2025.

### 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 <u>barnsleydiabetes.spa@nhs.net</u>
- Both parties should retain a signed copy of the form in the patient's record.

From (Specialist): To (GP):
Patient details
Name
Address
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 2 diabetes who would otherwise be advised to self-monitor at least 8 times per day	
Patients with insulin treated Type 2 diabetes who are living with a learning disability and recorded on their GP Learning Disability register.	
All children with type 1 diabetes	
Patients with Type 2diabetes who are pregnant and experiencing sever hypoglycaemic attacks.	
Fear of hypoglycaemia provokes clinically significant anxiety	
Capillary blood glucose monitoring within the school or nursery environment is challenging and is adversely affecting control	
<ul> <li>Exercise in children and young people in the following circumstances:</li> <li>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.</li> <li>For adolescents trying to lose weight but fearful of the hypoglycaemic effects of exercise</li> <li>For those who have had a severe episode of hypoglycaemia following sporting activity and cannot resume activity</li> <li>For those in whom there is concern regarding overcompensation with additional carbohydrate for activity</li> <li>Those involved in high endurance sporting activities where it is difficult to test blood sugar</li> <li>For those where exercise results in unpredictable hypoglycaemia</li> </ul>	

# **Confirmation of acceptance from GP**

The patient has met the criteria for the initiation of FreeStyle Libre® 2+ and is suitable to continue with use of the device. Specialist to sign below:
Specialist (Doctor/Nurse) name
Specialist (Doctor/Nurse) signature
Date
Patient Name:
Patient NHS number:
I, Drcan confirm I:
□ Accept the request to prescribe FreeStyle Libre® 2+ for the patient named above.
□ Reject the request to prescribe FreeStyle Libre® 2+ for the patient named above.
The reason for this being