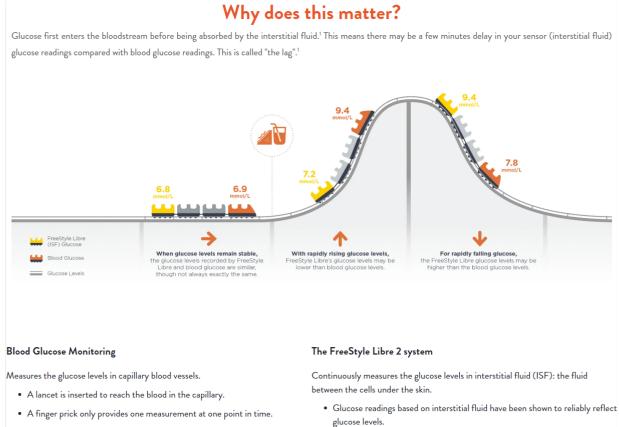






Protocol for initiating FreeStyle Libre[®] 2+ for glucose monitoring in ADULTS aged 19 years and over.

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.



- Requires a whole kit, including lancets and a blood glucose reader.
- 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+ by the specialist, whilst existing patients will be transferred to FreeStyle Libre[®] 2+ by primary care. FreeStyle Libre 2[®] has been discontinued and stocks will be depleted by the end of August 2025.^{1,6}

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.^{1 2} 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+ Plus sensor with your FreeStyle Libre[®] 2 reader <u>you will</u> <u>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+ 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[®] 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[®] 2+ but will need to use capillary monitoring even on days where they are not planning to drive.³

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

Initiation and supply of Freestyle Libre® 2+ in Barnsley Place:⁴

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 the following adult patients ^{4,5,7,9}
- Any patients with Type 1 diabetes, (for children see separate guidance);
- Patients with any form of diabetes receiving haemodialysis and requiring insulin therapy or taking a sulfonylurea.
- Patients with diabetes associated with cystic fibrosis requiring insulin therapy.
- Patients with insulin treated Type 2 diabetes who are living with a learning disability and recorded on their GP Learning Disability register.⁵
- Patients 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.⁴
- Patients with type 2 who are pregnant and experiencing severe hypoglycaemic attacks.
- Patients with Type 2 Diabetes on multiple daily insulin injections who have one of the following⁴:
 - □ Impaired hypoglycaemic awareness
 - Patients who would otherwise need help from a care worker or health professional to monitor their glucose.
 - Severe hypoglycaemia: defined as an episode of hypoglycaemia which requires assistance from another person to treat.⁴
 - Recurrent hypoglycaemia: defined as frequent hypoglycaemic events, occurring each week or month, which have an impact on quality of life.⁴
 - Patients who would otherwise be advised to self-monitor at least eight times a day.

Roles and Responsibilities

GP/Clinical Pharmacist Responsibilities

- Patient has been assessed by a specialist (new initiation) or been using Libre[®] 2 sensors for longer than 3 months and is deemed to be suitable for switch to FreeStyle Libre[®] 2+
- Patient has been using FreeStyle Libre[®] 2 or Libre[®] 2+ for a minimum of three months and it has been shown to improve the patient outcomes.
- For all new initiations, the specialist has written to the GP using the proforma in Appendix A detailing the reasons why FreeStyle Libre[®] 2+ has been initiated
- GP/Clinical Pharmacist to continue prescribing FreeStyle Libre[®] 2+ sensors in primary care.
- Type 1 diabetes patients will be reviewed by the specialist team at least annually. Type 2 diabetes patients may be discharged from the diabetes service before this time and will require an annual review by the practice.
- GP to prescribe replacement sharps bins for the disposal of sensors, as required (it is recommended that min of 5I size sharps guard bin is prescribed as the sensors do not fit through the opening of the 1 litre sharps bin)
- Transfer of patient from FreeStyle Libre[®] 2 to FreeStyle Libre[®] 2+ may be undertaken within 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 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 March 2025 all patients should be transferred promptly to FreeStyle Libre[®] 2+ as FreeStyle Libre[®] 2 sensors are no longer available (stocks will be depleted by June 2025).⁶ Each FreeStyle Libre[®] 2+ sensor lasts **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 prescribing of max 24 sensors per year.

Patient Responsibilities

- Patient/patient's carer will undergo training on the use of FreeStyle Libre[®] 2+ (on initiation or when requested by the patient after a switch to Libre[®] 2+).
- Patient will commit to ongoing regular follow-up and monitoring with the specialist diabetes team / primary care team and will be committed to using the FreeStyle Libre[®] 2+ device.
- FreeStyle Libre[®] 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 08001701177.

Monitoring of Outcomes

Patients started on FreeStyle Libre[®] 2+ should be monitored regularly to assess whether the device is suitable for them, and to ensure that its use is leading to improved outcomes. The following outcomes may be monitored where applicable:

- o Reductions in severe/non-severe hypoglycaemia
- o Reversal of impaired awareness of hypoglycaemia
- o Episodes of diabetic ketoacidosis
- o Admissions to hospital
- o Changes in HbA1c (see criteria for stopping below)
- o Testing strip usage
- o For adults, Quality of Life changes using validated rating scales (See Appendix B).
- o Commitment to regular scans and their use in self-management.

Patient Selection for criteria not mentioned above: Adults

For patients with Type 2 diabetes on multiple daily insulin injections, where one or more of the following criteria must also be satisfied:

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 patients where exercise results in unpredictable hypoglycaemia.

Criteria for stopping

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

- The patient no longer wishes to use the Freestyle Libre[®] 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 initiating clinician.

References

- The FreeStyle Libre[®] 2+ system for healthcare professionals. Available at: <u>https://freestylediabetes.co.uk/health-care-professionals/freestyle-libre/freestyle-libre-system</u> Last accessed on 28/02/2025.
- Freestyle Libre[®] Order a replacement sensor, available online at <u>https://www.freestylelibre.co.uk/libre/fsl2Replacement.html</u>. Last accessed on 28/02/2025.
- DVLA: Assessing fitness to drive: a guide for medical professional, Chapter 3 (Diabetes). Published August 2024. Available online at Last accessed on 28/02/2025.
- 4. NICE NG28: Type 2 Diabetes in Adults: Diagnosis and Management, Published 02/12/2015, last updated 29/06/2022. Available online at https://www.nice.org.uk/guidance/ng28/chapter/Recommendations#hba1c-measurement-and-targets Last accessed on 28/02/2025
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- 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 <u>https://www.nice.org.uk/guidance/ng3</u> Last accessed on 28/02/2025.
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- SY IMOC guidance for CGM un adults and children with Type 1 and Type 2 diabetes. Available at: <u>https://syics.co.uk/application/files/5117/0438/0314/SY CGM Guidance for Adults and Children with type 1 and type 2 diabetes V1.0.pdf</u>. Last accessed 30/01/2025

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 9th April 2025.

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+

From (Specialist):

To (GP): _____

Patient details

NameNHS 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
Any patients with Type 1 diabetes, (for children – see separate guidance	
Patient with diabetes associated with cystic fibrosis requiring insulin therapy	
Patients with any form of diabetes receiving haemodialysis and requiring insulin therapy or taking a sulfonylurea	
Patients with insulin treated Type 2 diabetes who are living with a learning disability and recorded on their GP Learning Disability register	
Patients 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).	
Patients with Type 2 diabetes who are experiencing severe hypoglycaemic attacks.	
Type 2 diabetes patients on multiple daily insulin injections with severe hypoglycaemia.	
Type 2 diabetes patients on multiple daily insulin injections with recurrent hypoglycaemia.	

Protocol for initiating Freestyle Libre® 2+ in Adults

Type 2 diabetes patients on multiple daily insulin injections with impaired hypoglycaemic awareness.	
Type 2 diabetes patients who would otherwise need help from a care worker or health professional to monitor their glucose.	
Type 2 diabetes patients on multiple daily insulin injections who would otherwise have to self-monitor at least eight times a day.	
 Exercise in adults 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 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 	

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, Dr can 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

APPENDIX B

Diabetes Self-Management Questionnaire (DSMQ)

self- diab care spec	following statements describe care activities related to your eetes. Thinking about your self- over the last 8 weeks, please ify the extent to which each ement applies to you.	Applies to me very much	Applies to me to a consider- able degree	Applies to me to some degree	Does not apply to me
1.	I check my blood sugar levels with care and attention. Blood sugar measurement is not required as a part of my treatment.	□3	□2	□1	□0
2.	The food I choose to eat makes it easy to achieve optimal blood sugar levels.	□3	□2		□0
3.	I keep all doctors' appointments recommended for my diabetes treatment.	□3	□2	□1	□0
4.	I take my diabetes medication (e. g. insulin, tablets) as prescribed. Diabetes medication / insulin is not required as a part of my treatment.	□3	□2	□1	0
5.	Occasionally I eat lots of sweets or other foods rich in carbohydrates.	□3	□2	□1	□0

self- diab care spec	following statements describe care activities related to your betes. Thinking about your self- over the last 8 weeks, please ify the extent to which each ement applies to you.	Applies to me very much	Applies to me to a consider- able degree	Applies to me to some degree	Does not apply to me
6.	I record my blood sugar levels regularly (or analyse the value chart with my blood glucose meter). Blood sugar measurement is not required as a part of my treatment.	□3	□2		0
7.	I tend to avoid diabetes-related doctors' appointments.	□3	□2		□0
8.	I do regular physical activity to achieve optimal blood sugar levels.	□3	□2	□1	□0
9.	I strictly follow the dietary recommendations given by my doctor or diabetes specialist.	□3	□2	□1	□0
10.	I do not check my blood sugar levels frequently enough as would be required for achieving good blood glucose control. Blood sugar measurement is not required as a part of my treatment.	□3	□2	□1	0

self- diab care spec	following statements describe care activities related to your etes. Thinking about your self- over the last 8 weeks, please ify the extent to which each ement applies to you.	Applies to me very much	Applies to me to a consider- able degree	Applies to me to some degree	Does not apply to me
11.	I avoid physical activity, although it would improve my diabetes.	□3	□2		□0
12.	I tend to forget to take or skip my diabetes medication (e. g. insulin, tablets). Diabetes medication / insulin is not required as a part of my treatment.	□3	□2	□1	0
13.	Sometimes I have real 'food binges' (not triggered by hypoglycaemia).	□3	□2	□1	□0
14.	Regarding my diabetes care, I should see my medical practitioner(s) more often.	□3	□2	□1	□0
15.	I tend to skip planned physical activity.	□3	□2		□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.

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APPENDIX C

The nine processes of care:

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