FreeStyle Libre 2 Plus® and Dexcom One +®

Inclusion Criteria in Type 2 Diabetes (Adults)

Traffic light classification- AMBER 3

Based on NICE Guidance - Type 2 diabetes in adults: management; Updated June 2022.

This guideline covers care and management for adults (aged 18 and over) with type 2 diabetes.

Patients with Type 1 diabetes should be initiated by a specialist*.

Children under 18 with type 2 diabetes should be managed in an individualised way under a paediatric specialist. It would be appropriate in such cases above for on-going prescriptions for CGM sensors to be managed by the GP.

*Specialist is defined by the APC as a clinician who has undertaken an appropriate formal qualification or recognised training programme within the described area of practice and has a working experience and knowledge within a speciality area. This may include a diabetes specialist nurse.

Licensed Indications

FreeStyle Libre 2 Plus® is Continuous Glucose Monitoring (CGM) sensor-based, factory calibrated system that measures glucose levels in interstitial fluid (not blood). FreeStyle Libre 2 Plus® is licensed in those aged 2 years and above. The system measures the glucose level via a sensor applied to the skin on the back of the upper arm which is left in place for 15 days and then replaced. The sensor deposits a 5mm filament into interstitial fluid which then takes a glucose reading every minute. The glucose levels are read by swiping a wireless reader or a Near Field Communication (NFC) enabled smartphone over the sensor at a distance of 1-4cm with no need to remove clothing. The most up to date glucose level is displayed together with recent trend data. The sensor stores information for 8 hours. Scanning at least once every 8 hours enables patients to continuously collect their glucose data.

The Dexcom ONE® + Continuous Glucose Monitoring System is a glucose monitoring system indicated for patients with Type 1 and Type 2 diabetes on multiple daily insulin injections (2 years +) & pregnant women. Dexcom ONE® + is designed to replace fingerstick blood glucose (BG) testing for diabetes treatment decisions. Interpretation of Dexcom ONE® + results should be based on the glucose trends and several sequential readings over time. Dexcom ONE® + also aids in the detection of episodes of hyperglycemia and hypoglycemia, facilitating both acute and long-term therapy adjustments. Dexcom ONE® + is intended for use by patients at home and in healthcare facilities.

Device Initiation

Initiation is restricted to clinicians who have completed self-directed training which is available via the following:

- Diabetes Technology Network
- EDEN Diabetes - Implementing Glucose Sensing in Primary Care' education package
- Glooko Academy

In Glokoo academy, following modules are relevant-

1. 1.Self-Monitoring Blood Glucose (SMBG)- would be good refresher
2. Flash Glucose Monitoring-essential for primary care

Registration is required-https://eu.my.glooko.com/patients

- Dexcom Education hub

In Dexcom Education hub the following modules are relevant-

1. Dexcom ONE+ rtCGM System
2. Dexcom Clarity

Furthermore CGM must only be initiated for patients who meet the inclusion criteria listed below. A starter pack containing the device and 1 sensor will be issued on initiation.

Practice set up

FreeStyle Libre

Individual practices can set up their Libre view account by going directly through the manufacturers website here.

LibreView set up: A short tutorial on how to setup an individual practice and connect patients is available here.

Dexcom One

Individual practices can set up their Clarity Clinic account by going directly through the manufacturers website here.

Clarity clinic set up: A short tutorial on how to setup an individual practice and connect patients is available here.

Clarity user guide can be found here.

Education on CGM has been provided (online- free registration required or in person).

- **Abbott FreeStyle Academy - https://progress.freestylediabetes.co.uk/sign-up**
- **Foreign Language material - https://www.freestyle.abbott/uk-en/support/accessibility.html**
- **FreeStyle Libre 2 new starter guide- https://www.youtube.com/watch?v=-e3yDD0vAIk&t=599s**
- **Primary Care resource developed by Abbott - https://pro.freestyle.abbott/uk-en/home/primary-care.html#primary-care-for-your-patient**

- **Dexcom ONE patient education and start up**
- **Dexcom ONE + patient education and start up**

Inclusion criteria

Offer CGM to adults with type 2 diabetes on multiple (2 or more per day) daily insulin injections if any of the following apply:

- they have recurrent hypoglycaemia (Defined as events which occur each week or month and have an impact on quality of life) or severe hypoglycaemia which requires assistance from another person
- they have impaired hypoglycaemia awareness
- they have a condition or disability (including a learning disability or cognitive impairment) that means they cannot self-monitor their blood glucose by capillary blood glucose monitoring but could use a CGM device (or have it managed for them)
- they would otherwise be advised on clinical grounds to self-measure with finger prick testing at least 8 times a day.

Offer CGM to adults with insulin-treated type 2 diabetes who would otherwise need help from a care worker or healthcare professional to monitor their blood glucose.

If a person is offered CGM but cannot or does not want to use this device, offer capillary blood glucose monitoring instead.

Other requirements:

1. Agree to regular reviews with their healthcare practitioner who manages their diabetes.
2. The CGM devices are designed to replace the use of **capillary blood glucose monitoring** so there is an expectation that demand/frequency of supply of test strips will be reduced. The patient is however advised to use a blood glucose meter to make diabetes treatment decisions if their glucose alerts and readings do not match symptoms or expectations. **Test strips should not normally be issued any more frequently than once every three months.**

Any form of Diabetes in Pregnancy

CGM will be offered to pregnant patients in accordance with the above recommendations. CGM for pregnant patients will be initiated by Specialists with special interest in Diabetes (Diabetologists, Diabetes Specialist Nurses) where patients are attending specialist diabetes

mellitus care. Additionally, and in accordance with NICE NG3, CGM will be offered to pregnant patients who are on insulin therapy but do not have Type 1 diabetes, if they have unstable blood glucose levels that are causing concern despite efforts to optimise glycaemic control

Patients with type 2 diabetes trying to conceive

Patients who are planning to conceive within the next 6 months AND who are under hospital supervision for their diabetes may be initiated on CGM by their specialist. In such cases the GP may continue with the ongoing supply. A review of eligibility should be completed post partum.

Patients on Dialysis

1. Where a patient has type 2 diabetes AND meets the eligibility criteria above, CGM may be initiated in Primary Care as above.

2. Where a patient has type 2 diabetes but DOES NOT otherwise meet the above eligibility criteria, CGM must be initiated by the renal team OR a diabetes specialist (which could include a DSN).
    1. The following clinical circumstances may be considered as suitable eligibility
    2. Once initiated by a renal or diabetes specialist, continued prescribing of sensors should be managed by the GP.

3. CGM should be considered for people on insulin and sulphonylureas who receive dialysis and who are having recurrent hypoglycaemia or loss of hypoglycaemia awareness (Gold score ≥4). Regardless of number of daily insulin injections
4. Where SMBG results show frequent (>5%) glucose readings below 4 mmol/L, frequent (>20%) glucose readings above 14 mmol/L, if they are unable to undertake SMBG twice a daily for 1-2 weeks periods, or if they have HbA1c < 42 mmol/mol (6.0%) or > 80 mmol/mol (9.5%).
5. Diabetes specialists may consider periodic (1-2x per year) 'diagnostic' CGM analysis for all people with diabetes on dialysis on insulin treatment in order to guide future treatment planning unless they are already using CGM systems. CGM may offer a better guide to insulin dosing on dialysis and non-dialysis days

Explicit criteria for review and discontinuation of the device

Use of the CGM will be for an initial 6-month trial period. If there is sustained benefit at 6 months, the initiating clinician must be assured that the patient is using the device correctly and scanning appropriately. The patient is required to bring all results to this appointment or share results on their mobile app or via Libreview or Clarity.

If the device is not being used correctly or the patient does not want to continue, capillary blood glucose monitoring should be offered instead.

Monitoring Requirements and Responsibilities

CGM will replace the majority of capillary glucose testing. Data are displayed on the scanning device. Using appropriate software (available as an app or desktop interface) these data can also be displayed and shared with clinical staff.

Contraindications

There are no specific contraindications in people with diabetes aged 4 and above.

Information given to patient and/or carer

Patients offered CGM will be asked to attend a structured education session to understand how to use and interpret data from the device. It is recommended that in order to get complete benefit of glucose monitoring technology, training should be completed either online or face to face as per availability and choice

Community Pharmacists' Role

Support appropriate use of the device – in particular the regular acquisition of data.

Patients' and/or carers' Role

Appropriate use of the device – in particular the regular acquisition of data and action based upon these data. To ensure results are available to the clinician at every review.

TO BE PRINTED FOR THE PATIENT TO TAKE AWAY FreeStyle Libre

Terms of Agreement

You, the patient, have fulfilled one or more of the criteria (as assessed by your healthcare practitioner) for a 6-month trial of FreeStyle Libre PLUS® under an NHS prescription.

Your healthcare practitioner will:

- Provide the links for online video training that you need to set you up on the FreeStyle Libre PLUS® glucose monitoring system. Face to face training could also be organised if difficulties are encountered with online training.
- Continue to give you on-going support and advice on managing diabetes whilst you are using the FreeStyle Libre PLUS® glucose monitoring system.
- Review you at the end of 6 months to assess your eligibility for continuing funding of the FreeStyle Libre PLUS® glucose monitoring system under an NHS prescription.

The patient (or carer on behalf of) will:

- Complete all training required for setting up the FreeStyle Libre PLUS® glucose monitoring system.
- Upload data from either the FreeStyle Libre PLUS® handset or via the LibreLink® app at least once every 2 weeks
- Share your data with your healthcare practitioner by adding the Practice ID code given to you to your LibreView® account settings
- Have blood taken for HbA1c at the start, ideally at 3 months and end of trial period at month 6
- Attend a minimum of 2 appointments (Telephone or Face to Face) with your healthcare practitioner within the trial period
- Attend a review appointment at 6 months to assess eligibility for ongoing funding
- Agree to change repeat prescriptions for blood glucose testing strips from every month to once in three months and to only order a further supply WHEN NEEDED.

Agreement Signed and dated
Diabetes specialist: _____

Patient: _____

Date: _____

TO BE PRINTED FOR THE PATIENT TO TAKE AWAY Dexcom ONE +

Terms of Agreement

You, the patient, have fulfilled one or more of the criteria (as assessed by your healthcare practitioner) for a 6-month trial of Dexcom ONE +® under an NHS prescription.

Your healthcare practitioner will:

- Provide the links for online video training that you need to set you up on the Dexcom glucose monitoring system. Face to face training could also be organised if difficulties are encountered with online training.
- Continue to give you on-going support and advice on managing diabetes whilst you are using the Dexcom glucose monitoring system.
- Review you at the end of 6 months to assess your eligibility for continuing funding of the Dexcom glucose monitoring system under an NHS prescription.

The patient (or carer on behalf of) will:

- Complete all training required for setting up the Dexcom glucose monitoring system.
- Share your data with your healthcare practitioner by adding the Clarity clinic share code in your Clarity account settings.
- Smartphone users data will automatically upload to Clarity clinic. Those using a receiver should upload their data every 2 weeks – (the receiver will hold up to 180 days of data).
- Have blood taken for HbA1c at the start, ideally at 3 months and end of trial period at month 6
- Attend a minimum of 2 appointments (Telephone or Face to Face) with your healthcare practitioner within the trial period
- Attend a review appointment at 6 months to assess eligibility for ongoing funding
- Agree to change repeat prescriptions for blood glucose testing strips from every month to once in three months and to only order a further supply WHEN NEEDED.

Agreement Signed and dated
Diabetes specialist: _____

Patient: _____

Date: _____

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Regional Medicines Optimisation Committee Position Statement: https://www.sps.nhs.uk/wp-content/uploads/2017/11/Flash-Glucose-monitoring-System-RMOC-Statement-final-2.pdf

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