FreeStyle Libre 2® 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

Patients with Type 1 diabetes or with any form of diabetes on dialysis who are already established and stable on FreeStyle Libre 2 or Dexcom ONE or where it is clinically appropriate for one of these devices to be used may also be prescribed. Specialist initiation is required for these cohorts. This guideline covers care and management for adults (aged 18 and over) with type 2 diabetes.

Licensed Indications

The FreeStyle Libre® 2 glucose monitoring system is indicated for measuring interstitial glucose levels in people (age 4 or older) with diabetes mellitus, including pregnant women. 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 two weeks and then replaced. The sensor deposits a 5mm filament into interstitial fluid which then records a glucose reading every minute. The glucose data is transferred automatically in real time for those using a Near Field Communication (NFC) enabled smartphone or by swiping an Abbott Reader 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 glucose readings for 8 hours, so for patients using an Abbott Reader, scanning at least once every 8 hours enables continuous glucose data.

The Dexcom ONE® Continuous Glucose Monitoring System (Dexcom ONE) is a glucose monitoring system indicated for patients with Type 1 and Type 2 diabetes on multiple daily insulin injections (2 years +) & pregnant women. However this guideline covers care and management for adults (aged 18 and over) with type 2 diabetes. 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.

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 for on-going prescriptions for FreeStyle or Dexcom sensors to be managed by the GP.

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

Furthermore FreeStyle Libre 2 or Dexcom One 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.

Clarity FAQ can be found here.

Inclusion criteria

Offer FreeStyle Libre 2 or Dexcom One 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 FreeStyle Libre 2 or Dexcom One 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 FreeStyle Libre 2 or Dexcom One 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.

Education on FreeStyle Libre 2 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**

Adults with Type 2 Diabetes who meet the eligibility criteria for FreeStyle Libre 2 as detailed above are eligible for Dexcom One only where Dexcom One is available at the same or lower cost as FreeStyle Libre 2.

Education on Dexcom One has been provided (online or in person).

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

If a person is offered FreeStyle Libre 2 or Dexcom One but cannot or does not want to use this device, offer capillary blood glucose monitoring instead.

Other requirements:

1. Where an FreeStyle Libre 2 is prescribed and used with an Abbott Reader – agree to scan glucose levels no less than 8 times per day and use the sensor >70% of the time.

2. Agree to regular reviews with their healthcare practitioner who manages their diabetes.

3. The FreeStyle Libre 2 and Dexcom One 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**

Explicit criteria for review and discontinuation of the device
Use of the FreeStyle Libre 2 or Dexcom One 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
FreeStyle Libre 2 and Dexcom One will replace the majority of capillary glucose testing. Data are displayed on the scanning device. Patients are asked to scan the FreeStyle Libre 2 no less than 8 times per day **if they are using an Abbott Reader** so that there is near continuous acquisition of glucose data for analysis and action. For those on FreeStyle 2 using a Near Field Communication (NFC) enabled smartphone, there is no need to scan.
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 FreeStyle Libre 2 or Dexcom One 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 – see patient agreements below

TO BE PRINTED FOR THE PATIENT TO TAKE AWAY FreeStyle Libre 2

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® 2 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® 2 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® 2 glucose monitoring system.
- Review you at the end of 6 months to assess your eligibility for continuing funding of the FreeStyle Libre® 2 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® 2 glucose monitoring system.
- Upload data from either the FreeStyle Libre® 2 Reader 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 ONE 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 ONE glucose monitoring system.
- Review you at the end of 6 months to assess your eligibility for continuing funding of the Dexcom ONE glucose monitoring system under an NHS prescription.

The patient (or carer on behalf of) will:

- Complete all training required for setting up the Dexcom ONE 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 30 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

Diabetes UK Consensus Guideline for Flash Glucose Monitoring Date (published September 2017): https://www.diabetes.org.uk/resources-s3/2017-09/1190_Flash%20glucose%20monitoring%20guideline_SB_V9%5B4%5D.pdf?_ga=2.137083376.1339632840.1505301182-2056973880.1505301182

Position statement of Association of British Clinical Diabetologists, https://abcd.care/sites/all/modules/civicrm/extern/url.php?u=2850&qid=115746

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Updated in July 2023 to reflect FreeStyle Libre 2 moving to real time monitoring.