Continuous Glucose Monitoring for Adults

Background

Individuals with diabetes on insulin need to regularly monitor their blood glucose levels to determine the amount of insulin they need to inject, to keep their blood glucose within an acceptable range and reduce the risk of short- and long-term complications.

Historically, there were three main types of blood glucose monitoring:

- self-monitored blood glucose testing (using skin prick tests),
- real-time continuous glucose monitoring (**rtCGM**)
- intermittently scanned continuous glucose monitoring (**isCGM**). isCGM is also sometimes known as 'flash'. The only isCGM available in the UK (FreeStyle Libre 2) has now been upgraded to rtCGM, although it can still be used as an isCGM for patients who prefer this.

Eligibility

In PTHB a choice of rtCGM or isCGM should be offered to people with diabetes requiring treatment with insulin. Choice should be based on: PTHB formulary; individual preferences; needs; characteristics; and the functionality of the devices available.

The following CGM devices are currently available on the PTHB formulary: -

Product	Replacing	Product Type	PTHB Formulary Position
FreeStyle Libre 2 Plus	Freestyle Libre 2	rtCGM & isCGM	**See** PTHB formulary
Dexcom ONE+	Dexcom ONE	rtCGM	
Freestyle Libre 3 Plus	Freestyle Libre 3	rtCGM & isCGM	

In 2021 Heath Technology Wales (HTW) reviewed "*FreeStyle Libre flash glucose monitoring for the management of diabetes*" and determined.

> *The evidence supports the routine adoption of Freestyle Libre flash glucose monitoring to guide blood glucose regulation in people with diabetes who require treatment with insulin.*

Subsequent NICE guidance has been published which recommends: -

- **Type 1 diabetes** - offer adults a choice of rtCGM or isCGM based on their individual preferences, needs, characteristics, and the functionality of the devices available. [NICE NG17]
    - if several devices meet the individual's needs and preferences, the device with the lowest cost should be offered (latest prices can be found in the BNF online or Drug Tariff (Part IXA-Appliances))
- **Type 2 diabetes** - consider rtCGM as an alternative to isCGM glucose monitoring for adults, if it is available for the similar or lower cost. [NICE NG28]
- **Pregnancy** - offer rtCGM to all pregnant women with type 1 diabetes to support them meet their pregnancy blood glucose targets, while also improving neonatal outcomes. Offer isCGM if unable to use rtCGM [NICE NG3].
    - Consider rtCGM for pregnant women who are on insulin therapy but do not have type 1 diabetes, if:

- they have problematic severe hypoglycaemia (with or without impaired awareness of hypoglycaemia) **or** they have unstable blood glucose levels that are causing concern despite efforts to optimise glycaemic control.

In light of the updated NICE guidance above HTW have no plans to review real time continuous glucose monitoring because an additional HTW appraisal is unlikely to add value alongside the recent NICE recommendations https://healthtechnology.wales/reports-guidance/real-time-continuous-glucose-monitoring/

Type 1 Diabetes – capillary blood glucose measurements

Patients with type 1 diabetes who are using CGM will still need to take capillary blood glucose measurements (although they can do this less often). This is because:

- capillary blood glucose measurements are needed to check the accuracy of their CGM device
- capillary blood glucose monitoring will be required as a back-up (e.g when blood glucose levels are changing quickly or if the device stops working).

	Freestyle Libre 2 Plus	Dexcom ONE +	Freestyle Libre 3 Plus
PTHB Formulary Position	**See** PTHB formulary		
Wear Time	15 days	10 days (plus 12 hour grace period)	15 days
Sensor Memory	8 hours	12 hours	15 days
Type of device	rtCGM & isCGM	rtCGM	rtCGM & isCGM
Sensor Dimensions	5.0mm (H) x 35mm (D)	4.6mm (H) x 24mm x 27.3mm	2.9mm (H) x 21mm (D)
Approved Wearable Site	Back of upper arm	Back of upper arm Abdomen Upper buttocks (child age 2 – 6 yrs only)	Back of upper arm
Sensor warm up time	60 minutes	30 minutes	60 minutes
Water Resistance	Up to 1 metre of water for 30 minutes. Can be worn while bathing, showering and swimming	Waterproof can be submerged under 2.4 meters of water for up to 24 hours	Up to 1 metre of water for 30 minutes. Can be worn while bathing, showering and swimming
Optional alarms	• Low glucose alarm, range 3.3–5.6 mmol/L • High glucose alarm, range 6.7–22.2 mmol/L • Signal loss alarm	Alerts can be customised via phone app.	• Low glucose alarm, range 3.3–5.6 mmol/L • High glucose alarm, range 6.7–22.2 mmol/L • Signal loss alarm
Connectivity	6 metre range	6 metre range	10 metre range, reconnects in 30 seconds
Sharing of data with Healthcare Professional	via LibreView web platform	via Dexcom Clarity App	via LibreView web platform
Caregiver app	Via www.LibreLinkUp.com	Via Dexcom Follow App	Via www.LibreLinkUp.com
Patient Education	https://www.freestyle.abbott/uk-en/myfreestyle/myfreestyle.html	https://www.dexcom.com/en-GB/dexcom-one-plus-learn-the-basics	https://www.freestyle.abbott/uk-en/myfreestyle/myfreestyle.html
HCP Education	https://pro.FreeStyle.Abbott/uk-en/scientific-resources-education/libre-academy	https://www.dexcom.com/en-GB/healthcare-professionals/education-resources	https://pro.FreeStyle.Abbott/uk-en/scientific-resources-education/libre-academy
Phone Compatibility	Mobile Device & OS Compatibility User Manual www.diabetescare.Abbott/support/manuals/uk	Phone comparability https://www.dexcom.com/en-GB/compatibility	Mobile Device & OS Compatibility User Manual www.diabetescare.Abbott/support/manuals/uk
Reader Available	✓ (scanning)	✓	✓ (streaming)
Customer Care Contact	**0800 170 1177** Mon–Fri 8am–8pm, Sat 9am–5pm adchelpuk@abbott.com	**0800 031 5763** https://www.dexcom.com/en-gb/contact-us-direct	**0800 170 1177** Mon–Fri 8am–8pm, Sat 9am–5pm adchelpuk@abbott.com

Initiation

The healthcare professional who is recommending a CGM device upon reviewing the patient is responsible for the first supply and arranging any suitable training for the patient.

Where a formulary status is '**amber**' denoting "specialist initiation", for the purposes of these devices - specialists can be healthcare professionals in secondary care, community, or primary care healthcare professionals who have undertaken appropriate training for the initiation and monitoring of these devices and can make shared decisions with patients.

- Identify the most appropriate device with the person living with diabetes (consider the person's preference, benefits/drawbacks of alerts and alarms, ability to share data with family and carers, potential issues with scanning/dexterity, and cost).
- Download the device's compatible mobile app for use with a smart device, prior to fitting. If a smart device is not available, arrange for a compatible reader before fitting. See manufacturers' specific guidance on how to apply the sensor and, for rtCGM, transmitter.
- Advise on warm-up time for the sensor (see table around device differences) and set low and high alarms (refer to individual device user guides) based on individualised target glycaemic range.
- Signpost the user and/or their family and carers to appropriate education to enable self-management (see links in table).
- Provide information on future need for capillary glucose testing, driving (e.g. Group 2 drivers), etc. (see in FAQ).
- Consider linking to the device's cloud-based system (if local data-sharing guidelines allow) so that data can be shared from the person's own account to the healthcare professional's clinic account, to allow for remote review/consultations.
- Ensure the person understands when the data will be reviewed, and that CGM does not mean a professional will be viewing/monitoring their data continuously outside of consultations and will only take place usually at review within clinic.
- Arrange for timely review/follow-up.
- Provide information on disposal and sharps box.
- Advise on when blood glucose monitoring should continue.
- Advise who to contact if there is a faulty sensor (as per FAQ).

Patient Review

Interpret the data provided (e.g. time in range) being able to discuss areas such as limited data, inappropriate alarm settings, timing of insulin doses, incorrect insulin administration, under or overreacting to glucose levels, hypos, dietary changes.

- Assess machine suitability and overcome any questions patients may have.
- Review BGM.
- Provide educational support where needed

Frequently Asked Questions

Sensor is faulty or has fallen off

- **FreeStyle Libre 2 and 2 plus** - do not prescribe to replace faulty sensors (e.g falls off) and transmitters. The patient or carer should contact Abbot directly for a replacement.
  Call Abbott Customer Careline on 0800 170 1177 on the day that a problem is identified.
  The displaced/faulty FreeStyle Libre 2 Plus sensor should be kept and instructions of the Abbott Customer Careline representative should be followed.
  If a replacement sensor is issued, these should be received from Abbott within 3-5 days
- **Dexcom ONE and ONE+.** Faulty sensors (including those that fall off early and those that stop working) should be reported to the Dexcom technical support team directly on 0800 031 5763 or complete a Product Support Request. Replacements will be posted to the home address directly on a case-by-case basis

All healthcare professionals should also be aware of MHRA advice on reporting suspected adverse incidents and safety concerns to the MHRA's Yellow card scheme.

Quantities of blood glucose test strips/lancets to supply

Patients who use CGM still need to take blood glucose measurements, but less often. Blood glucose monitoring is required to check the accuracy of their CGM device and as a backup when blood glucose levels are changing quickly, or the device stops working. When CGM is commenced, prescribed quantities of blood glucose test strips/lancets should reduce.

Using CGM to monitor blood glucose levels for the purpose of driving

The Driver and Vehicle Licensing Agency (DVLA) has published guidance relating to the use of CGM to monitor blood glucose levels for the purpose of driving. Diabetes mellitus: assessing fitness to drive - GOV.UK

How should patients remove their device?

Manufacturers' advice:

- https://www.dexcom.com/en-GB/faqs/how-do-i-properly-remove-sensor-adhesive
- https://www.freestyle.abbott/content/dam/adc/freestyle/uk/documents/legacy/Adhesion_Guide_(Page_4).pdf and https://www.freestyle.abbott/uk-en/support/faq.html

Where an adhesive remover is required to be used with these devices this should be purchased over the counter.

Also see the MHRA advice on the use barrier methods which may affect device performance for FreeStyle Libre: https://www.gov.uk/government/news/alert-to-users-of-freestyle-libre-flash-glucose-monitoring-system-regarding-skin-reactions-to-sensor-adhesive