Continuous Glucose Monitoring (CGM) for people living with type 2 diabetes implementation document

For the boroughs of Barnet, Camden, Enfield, Haringey and Islington

Scope and rationale

The scope of this policy is for adults, children and young people living with type 2 diabetes (T2DM) and access to continuous glucose monitoring (CGM).

This document is based upon the pan-London recommendations for continuous glucose monitoring (CGM) sensors for people living with type 2 diabetes, and is intended to aid local this cohort of patients, in line with NICE guidelines (NG28, NG3, NG18).

Purpose

This implementation document is for use by secondary care, community diabetes specialist services, and primary care diabetes health care professionals to assess if people living with T2DM are suitable for CGM.

The document aims to identify patient groups who would benefit most from NICE guidance, empowering informed choice of device for individuals, ensuring equitable access for all groups, and considering clinical characteristics that may be important for the safety and effectiveness of CGM technologies.

Clinicians should make shared decisions with individuals matching the criteria within this policy prior to prescribing CGM. Prescribing should only be undertaken where the criteria have been met, where there is robust evidence that the CGM is effective, and the individual has the potential to benefit from the device.

Eligible cohort of patients

Please refer to the NHS eligibility for CGM for adults, children and young people living with type 2 diabetes chart to identify eligible patient cohorts. The chart is taken from the pan-London implementation document for continuous glucose sensors for people living with type 2 diabetes.

Risk stratification

The following approach to risk stratification, implemented for system capacity reasons and to support the phased introduction of CGM for adults living with type 2 diabetes within the NCL ICS has been agreed by the NCL Diabetes Network:

Recurrent, severe or impaired hypoglycaemia awareness (as defined by Gold/Clarke score ≥4) and individuals with a history of severe hypoglycaemia (2 or more insulin injections)
Individuals living a learning disability recorded on their GP Learning Disability Register (1 or more insulin injections)
Pregnancy (12 months' worth of sensors)
Children and Young People (under specialist services) see their criteria
Individuals with a condition or disability includes (learning disability or cognition impaired) that means they cannot self-monitor CBG's themselves but can use a CGM device or have it scanned for them.. (2 or more insulin injections)
Individuals on haemodialysis been advised to self-monitor CBG's ≥8 times per day (1 or more insulin injections)
Individuals who been advised to self-monitor CBG's ≥8 times per day (basal bolus regimes) (2 or more insulin injections)
Individuals requiring help from a care worker or health care professional to monitor their blood glucose levels. (1 or more insulin injections)

CBG - capillary blood glucose monitoring

Initiation of CGM

Initiation of CGM will be led by the children's diabetes clinics and adult community diabetes teams and secondary care. Primary care diabetes health care professionals who have completed the training and have the skills to initiate as per criteria may also initiate CGM.

Adult diabetes specialist teams do not have the capacity to review all patients in the eligible cohorts and therefore, there will be a phased implementation with priority patients reviewed first or, opportunistically, when the patients are attending for their scheduled regular reviews. Diabetes teams in the community and hospital have started requesting general practice to continue prescribing CGM sensors in primary care for the eligible cohort of patients.

For now, primary care providers are advised not to refer patients to specialist services primarily for CGM initiation. Specialist teams will review and initiate new referrals and existing patients in due course, if they meet the criteria based on clinical need and if patients meet the NICE criteria.

Transition to adult care for children

As part of the transition to adult care, children/young people should be advised and documented to continue their CGM.

Actions for specialist diabetes teams

- Initiate and train the patient on CGM use using shared decision making.
- It is the responsibility of the diabetes specialist healthcare professional to initiate the most appropriate CGM device after considering the individual's needs and preferences. Please refer to **table 1** below and Appendix 1 for guidance on selecting the most suitable CGM sensor for a patient, including the key differences between the formulary devices —Freestyle Libre 2 Plus and Dexcom ONE+.

Table 1 Formulary choices of CGM devices for type 2 diabetes

Device/Sensor Name	Key Features	Maximum quantities
Dexcom ONE +	• 10-day sensor with built in transmitter • Optional reader if no smartphone access • Data sharing with HCP's via Dexcom Clarity software carers/family member who is the next of kin or has LPA via Dexcom Follow app. • Indicated for ages 2 years and older	3 per 30 days/ 36 per year 1 kit = 1 sensor (10 day's supply)
Freestyle Libre 2 plus	• 15-day sensor with built-in transmitter • Optional reader if no smartphone access • Optional high and low glucose alarms • Data sharing with HCP is via Libreview and with carers/family via Librelinkup • Indicated for ages 2 years and older	2 per 30 days/ 24 per year 1 kit = 1 sensor (15 day's supply)

Formulary devices will be periodically reviewed as new evidence and technologies emerge and taking national recommendations into consideration.

- Prescribing clinicians must ensure that individuals living with T2DM receive appropriate education on the use of their CGM device from the healthcare professional initiating it. Prior to starting CGM, individuals should have completed suitable diabetes education—provided in person by specialist or community diabetes services, or via an approved online service or provider—or have been assessed as having sufficient self-efficacy in diabetes self-management.
- Some high-risk patients benefit from CGM sooner, and the education will happen in parallel.
- Individuals should receive education tailored to their specific needs regarding the use of their CGM device, provided by the healthcare professional responsible for prescribing it.

- Provide initial 30 days' supply of CGM sensors (either Freestyle Libre 2 Plus or Dexcom ONE+) and then request continuation of prescribing in primary care.
- Ensure the criteria the patient meets to start CGM is detailed on the patient initiation letter and shared with primary care.
- Request a reduction in the prescribing of blood glucose monitoring strips (BGTS) and lancets for most patients.
- Follow up the data platforms and ensure that by six months of treatment, patients are eligible to continue treatment and provide feedback to general practice on usage of CGM, review improvement in Hb1Ac and/or reductions in hypoglycaemia.

Actions for primary care clinicians

GPs, PCN pharmacists and nursing staff are not expected to initiate CGM for adults living with type 2 diabetes unless:

- they have experience in initiating insulin and making dose adjustments, and
- undergone appropriate training (such as EDEN training) to initiate and interpret CGM and
- know how to interpret the data on the data platforms for Freestyle Libre 2 Plus and Dexcom ONE+ and act upon the results and
- follow the local criteria for suitability.

Where CGM has been initiated by a specialist, general practice may continue prescribing of CGM sensors in primary care for the eligible cohort of patients. In line with type 1 diabetes, primary care is advised to provide a separate prescription of 60 days' worth of sensors

Once patients are stable, they may be discharged to primary care by a diabetes specialist team. Primary care clinicians can review the patient's device(smartphone or reader) or sharing platform (as they would review blood glucose readings on their meters). Education and training for primary care to interpret data can be accessed by Eden and local education will also be explored.

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Patient agreement

When initiating CGM, the person living with T2DM should agree:

- to ensure that the CGM data is made available for the healthcare professional at reviews as part of their clinical care plan
- an expectation that people use the device at least 70% of the time and collect at least 70% of data
- the criteria under which CGM is being initiated, and any continuation criteria (above the requirement to collect 70% of data) should be recorded at care

reviews and shared decision made on future monitoring Additionally, patients will be reviewed for improvement in Hb1Ac and reductions in hypoglycaemia.

The suitability of the device should be assessed at each review, when monitoring is reviewed and changed to self-monitoring of blood glucose; information must be shared with the primary care team.

Training for health professionals on CGM

Training resources shared by North East London Integrated Care Board (NEL ICB) can be used by health professionals to update their knowledge on CGM.

Ongoing prescribing of test strips and lancets for capillary blood glucose testing

Everyone living with type 2 diabetes and eligible for CGM will still require ongoing FP10 prescriptions for capillary blood glucose (CBG) testing (lancets and strips). Ongoing prescribing is required to ensure a safe mechanism of glucose testing should the CGM device or reader fail/be damaged/lost, and to facilitate glucose testing when use of the CGM is not appropriate, or CGM reading does not reflect symptoms.

Most patients require two hundred test strips (a prescription of 50 strips (1 box) approximately every 3 months) and lancets per year for capillary blood glucose (CBG) testing. Please amend prescription quantities appropriately in primary care and move to variable repeat or acute prescription. Some individuals may require more than this, particularly for treatment adjustments or to confirm hypoglycaemia or for occupational reasons. The diabetes specialist team will advise if this is the case.

Please refer to NCL ICS Diabetes blood glucose and ketone meters, testing strips and lancets recommendations for further guidance and meter and lancet recommendations.

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 click.

Switching between FP10 prescribable CGM devices

Patients currently receiving CGM for T2DM who feel that an alternative manufacturer's system is better suited to managing their diabetes should be advised to discuss this with their diabetes specialist at their next routine appointment.

Specialists may switch patients to an alternative manufacturer's device where considered suitable. Primary care clinicians should only switch the patient's

prescription to an alternative manufacturer's device when advised to do so by the patient's diabetes specialist.

Information on faulty or sensor falling off

Freestyle Libre 2 Plus

In the event of a sensor issue, e.g. faulty or one that comes off skin, advise the patient/carer to directly contact Abbott Customer Care on 0800 170 1177 or visit: Contact | FreeStyle Libre | Abbott and report on the day that the problem is noticed. The displaced or faulty FreeStyle Libre 2 Plus sensor should be retained, and the patient should follow the instructions provided by the Abbott Customer Care representative. If a replacement sensor is warranted, it will be received from Abbott within 3-5 days.

Dexcom ONE +

Patients experiencing issues with sensors should report this to Dexcom Technical Support online at: Product Support Request or on 0800 031 5763. The displaced/faulty Dexcom ONE+ sensor should be kept as may be required to be returned to the company for investigation.

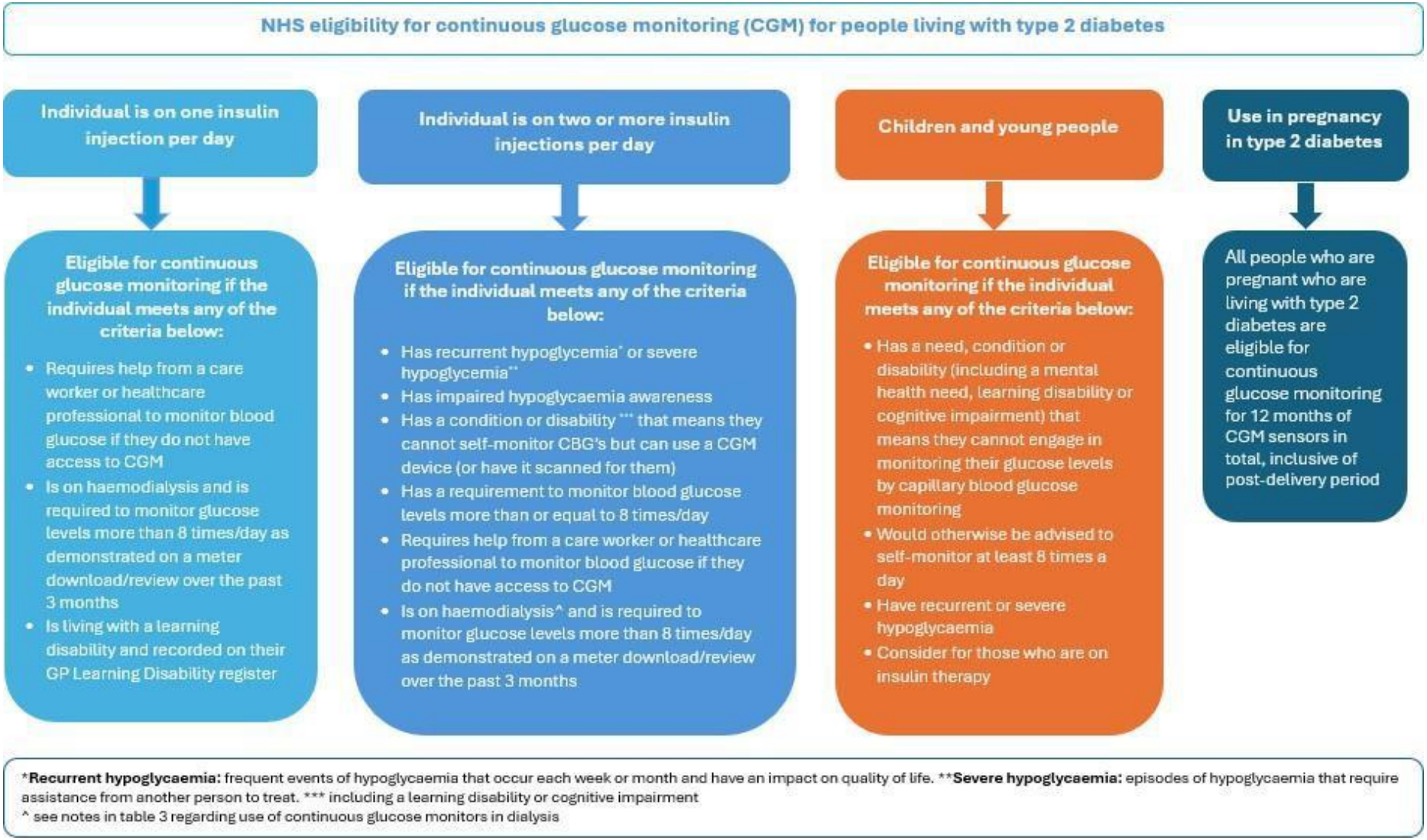
Contact information for additional support:

Primary Care Clinicians including Community Pharmacy	Medicines Optimisation Team (MOT) nclicb.medsoptimisation@nhs.net
Secondary Care Clinicians	Specialist Diabetes Teams - at Trust
Community clinics	Barnet: CLCHT.BarnetDiabetes@nhs.net Camden cnwl.camdendiabetes@nhs.net Enfield: rf-tr.diabetes@nhs.net Haringey and Islington: whh-tr.diabetesidss@nhs.net
Patients	To contact their GP practice or community diabetes clinic.

We would like to thank North East London ICB for permission to use of their educational resources in North Central London.

NHS eligibility for CGM for adults, children and young people living with type 2 diabetes

Eligibility criteria based on NICE criteria and pan-London implementation document for continuous glucose sensors for people living with type 2 diabetes



Appendix 1: Key features of standalone CGM available on FP10 for people living with type 2 diabetes

This comparison chart is to aid prescribers with choice of CGM for an individual patient using shared decision making.

Device	Dexcom ONE+	Free Libre 2 Plus
Sensor insertion	One-touch device insertion	Sensor device and applicator come separately, once joined together then one-touch device insertion
Sensor size	27.4mm (L) 24.1mm (W) 4.7mm (H)	35mm (diameter) 5mm (H)
Sensor wear time	10 days+ 12-hour grace period	15 days
Prescription quantities	3 sensors per 30 days	2 sensors per 30 days
Age(in years)	2+ and over and pregnancy	2+ and over and pregnancy
Frequency of glucose readings	Every 5 minutes	Every 1 minute
Is scanning of the sensor required?	No-The glucose measurement is automatically sent to the user's receiver/smart phone app every 5 minutes. Optional **Real-time** reader (receiver) if no smartphone access	No except for when starting the sensor for the first time, or if patient needs to backfill their data when using smart phone (if they move out of Bluetooth range of their phone). In all other situations, patients open the app to see their glucose reading. Patients using a reader need to scan this over their sensor to see their glucose reading. Doing so every 8 hours gives them a complete glucose profile.
MARD**	8.2%	8.2%
Warm-up time	30 mins	1 hour
Water resistance	Waterproof - 2.4m / 24 hours	Water resistant - 1m / 30 mins
Wear locations	Upper buttocks (2-6 years), back of arm and abdomen	Back of upper arm
High and low alarms	Yes	Yes
Display devices	Smartphone or Dexcom ONE+ receiver	Smartphone or Freestyle Libre 2 reader
Data Sharing	Data sharing to healthcare professionals via the Dexcom Clarity software. Carers/family members who are the next of kin or have LPA can follow the Dexcom Follow app	Healthcare professionals, relatives and carers
App required for using with a phone	Dexcom One + App	FreeStyle LibreLink app
What models /makes of phones support the App?	Models and makes of compatible phones can be found here Dexcom find compatible devices	Models and makes of compatible phones can be found: Abbott User Manual
Platform for clinical teams to access data	Clarity for type 2 diabetes	LibreView, for type 2 diabetes
Is there a reader available?	Yes – Can be ordered via local Rep - no scanning required	Yes – Can be ordered via local Rep requires scanning every 8 hours for accurate readings to be displayed. General practice can order via Libre Hub
Is calibration required	This is optional. Calibration may align the sensor reading to your blood glucose meter reading	

Device	Dexcom ONE+	Freestyle Libre 2 plus
Glucose results affected by medication	Yes - hydroxyurea	Yes - high dose vitamin C (doses of 1000mg/day or more)
** MARD – Mean Absolute Relative Difference – measures on average how far away the CGM glucose sensor reading is from a blood glucose reading, irrespective of whether the difference observed is more or less than the blood glucose reading. A lower value suggests a greater degree of analytic performance (accuracy).		

High and low alarms	Dexcom ONE+	Freestyle Libre 2 plus
In cases where the app indicates a low reading when the blood glucose meter shows otherwise, it may be due to pressure on the sensor. Users are advised to be mindful of the sensor and avoid it being bumped or laid on when sleeping to ensure accurate readings.		
	• If your display device (phone or Dexcom ONE+ receiver) is on silent or vibrate, you won't hear high or low glucose alerts. • Turn on display device sound to hear alerts. • Check your display device sound settings, or you may miss an alert.	When patients (or their healthcare professional) switch on either the high or low glucose alarm on the LibreLink smartphone app, the app will ask them to activate "do not disturb" so that alarms are still audible even when the phone is put into silent mode.
Low alerts	Yes - customisable between 3.3 - 8.3 mmol/L No urgent low alert	Yes - customisable between 3.3 - 5.6 mmol/L No urgent low alert FreeStyle Libre sensors take glucose readings every minute, and alarms are triggered the minute the glucose crosses the threshold set by the patient, so there is little need for predictive alarm
High alerts	Yes - customisable between 5.5 - 22.2 mmol/L + optional delayed first alert After you acknowledge your first alert, it repeats if your sensor reading stays high for this long. Select a repeat time between 15 minutes and 4 hours	Yes - customisable between 6.7 - 22.2 mmol/L FreeStyle Libre sensors take glucose readings every minute, and alarms are triggered the minute the glucose crosses the threshold set by the patient, so there is little need for predictive alarm
Total number of alerts	3- Low, High and Delay 1st High alert	2