NHS England London

A pan-London implementation document for continuous glucose sensors for adults with type 1 diabetes: written pathway

Version 7.0

Circulated date: 12.10.22

Date Agreed at LCEG: 5.10.22

Review Date: 5.4.2023

This document will be reviewed and re-released to reflect new and emerging evidence as appropriate. Please email england.londoncagsupport@nhs.net to request the most recent version.

This London guide is designed to complement and not replace local guidance and professional judgement. It will be updated to align with other national and regional guidance once published.

A pan-London implementation document for continuous glucose sensors for adults with type 1 diabetes

Scope and rationale:

The National Institute for Health and Care Excellence (NICE) Guidance for adults with type 1 diabetes (NG17) changed in 2022 to include access to continuous glucose monitoring (CGM) technologies for all adults living with type 1 diabetes. This is an implementation document which aims to support NG17, empowering informed choice of device for adult individuals with type 1 diabetes, ensuring equitable access for all groups and considering clinical characteristics that may be important for the safety and effectiveness of CGM technologies.

The scope of this document is for adults with type 1 diabetes only. A companion implementation document will be undertaken for CGM access for Children and Young People living with type 1 diabetes.

A full cost effectiveness evaluation of the expansion of access to CGM was undertaken as part of the NG17 guidance development process. A link to this evaluation can be found here. The NICE guidelines also include a local resource impact template - a link to this resource can be found here. Organisations can input estimates into the local resource impact template estimate the local impact of implementing the guideline.

When choosing a continuous glucose monitoring device, clinicians and individuals should use shared decision making to identify the individual's needs and preferences, and an appropriate device should be offered to meet these. If multiple devices meet an individual's needs and preferences, offer the device with the lowest cost.

This implementation document has three parts:

- This document (written pathway)
- Implementation flowchart (link)
- Accompanying device list (link)

This document should also be considered alongside the Type 1 Diabetes Outpatient Transformation Framework (link), approved by the London Diabetes Clinical Executive Group in April 2022.

Suggested Implementation of NICE CG17 (2022):

Appendix 1 (page 6 of this document) gives definitions and explanations of acronyms and clinical terms used in this document.

1. **Determine whether individual with type 1 diabetes is in one or more of the following clinical categories:**

- Problematic hypoglycaemia (see below for definition)

- Pregnant[1]
- Currently using continuous subcutaneous insulin infusion (CSII, also known as an insulin pump), with or without CGM-connected functionality
- Clinical need to share CGM data with family, friends or carers (e.g. physical impairment; learning difficulties; vulnerable or frail adult)

Problematic hypoglycaemia is defined as:

- One or more episodes of severe hypoglycaemia in preceding 12 months and/or
- Impaired hypoglycaemia awareness (Gold score ≥ 4) and/or
- More than one episode of asymptomatic hypoglycaemia per week
- Fear of hypoglycaemia[2]

2. Suggested approach to CGM for the above categories:

Category:	Suggested approach:
Problematic hypoglycaemia	Offer rtCGM system that has **mandatory fixed and predictive** low glucose alert feature (see **LIST 1**)
Pregnancy	If no problematic hypoglycaemia: Offer rtCGM system with optional non-predictive high and low glucose alerts (see **LIST 2**). Consider the relative cost and individual's experience of rtCGM devices that require adjunctive capillary blood glucose testing versus those that do not. If problematic hypoglycaemia: Offer rtCGM system that has **mandatory fixed and predictive** low glucose alert feature (see **LIST 1**)
CSII system	Offer rtCGM that is compatible with CSII system being used (see **LIST 1**)
Data sharing with relatives/carers/friends	Offer rtCGM with additional data-sharing feature (see **LIST 1** **or** **LIST 2**) or isCGM with additional data-sharing feature (see **LIST 3**).

[1] Please note, this refers to pregnant women with type 1 diabetes ONLY. It does not apply to pregnant women with gestational or type 2 diabetes. Please also note that from 2023/24 onwards, funding for CGM in pregnant women with type 1 diabetes will revert from a National funding stream to local commissioning structures.

[2] Choudhary P et. al. 2015. Evidence-informed clinical practice recommendations for treatment of type 1 diabetes complicated by problematic hypoglycaemia. *Diabetes Care.* Jun;38(6):1016-29. DOI: 10.2337/dc15-0090

3. **All individuals with type 1 diabetes who do not fall into the clinical categories outlined in section 1:**

- Suggest initially offering individual a choice of isCGM or rtCGM – individual preference of scanning or real-time data display

- If individual would prefer isCGM, offer a device from **LIST 3**

- If individual would prefer rtCGM, offer a device that meets the following criteria:

  1. Optional high and low glucose alerts
  2. The rtCGM system does not need to have connectivity/compatibility to a hybrid-closed loop or CSII system.
  3. The rtCGM system allows individual to view their own rtCGM data and share data with healthcare professionals, but does not feature a relative, friend or carer data-sharing system.
  4. The rtCGM system is available on FP10

  Examples of these devices can be found in **LIST 2**. Consider the relative cost of the device and the individual's experience of rtCGM devices that require adjunctive capillary blood glucose testing versus those that do not.

When deciding on a device with the individual with type 1 diabetes:

In discussion with the individual, it will be important to highlight certain aspects:

1 The need for greater amounts of continued capillary blood glucose testing with certain rtCGM devices (see device list – link);
2 That some isCGM and rtCGM devices will require a compatible smartphone (see device list – (link);
3 Discuss the need for support during initiation and initial management of blood glucose monitoring by a team with expertise in use of CGM.

- If discussing CGM at non-specialist level, clinicians and individuals should make a joint decision whether the individual and clinician wishes to have the support and input of a team with expertise in CGM.

- isCGM or rtCGM device available on FP10 can be initiated in non-specialist care if the individual does not wish to be referred to another care setting and the non-specialist team are able to provide expertise in CGM initiation and ongoing support.

- Alternatively, individuals can be referred to a team with expertise in initiation of CGM and (if required) also receive ongoing support with blood glucose monitoring. The FP10 prescription for CGM can continued by the GP.

We suggest that NICE NG17 2015 guidance should initially be equitably implemented to address population hypoglycaemia risk **(greatest clinical and cost benefit).**

Where prioritisation of individuals for CGM access is required, we suggest the following:

1 CGM access for individuals with problematic hypoglycaemia and fear of hypoglycaemia (as per NICE NG17 2015 guidelines).

2 Ensure isCGM or rtCGM access for individuals in line with NICE NG17 2015 recommendations for those of non-white ethnicity, individuals in most deprived areas and those not currently under the care of specialist services. This suggestion aims to reduce inequality of access. The Type 1 Diabetes Outpatient Transformation Framework includes pathways to identify and minimize health inequalities.

3 Ensure access to an appropriate CGM system (isCGM or rtCGM) for vulnerable type 1 populations, including people that are homeless, have severe and enduring mental illness, and those that are in residential and nursing dependent care, and in prisons. Again, this suggestion aims to reduce inequality of access to CGM.

Appendix 1: Clinical Terms and acronyms

Acronyms in this implementation document have been used in line with those in the NICE CG17 to provide consistency.

CGM	Continuous Glucose Monitoring A continuous glucose monitor is a device that measures glucose levels via a sensor worn on the body, and sends the readings to a display device ('reader') or smartphone via a transmitter.
rtCGM	real-time Continuous Glucose Monitoring This allows a continuous display of real-time glucose readings via a display device. Scanning a sensor to display the glucose result is not required.
isCGM	Intermittently-scanned Continuous Glucose Monitoring Also known as 'flash' glucose monitoring. This allows an intermittent display of glucose readings. The sensor records glucose readings continuously, but the sensor must be scanned by the individual (using a reader device or smartphone) to display the reading.
CSII	Continuous Subcutaneous Insulin Infusion This is also known as an 'insulin pump' device. Insulin pumps deliver a continuous background flow of insulin, and intermittent 'bolus' insulin, subcutaneously via a thin cannula attached to the abdomen, or via an insulin-containing 'pod' worn on the upper arm. The individual controls the amount and timing of insulin delivery.
Capillary blood glucose testing ('CBG' testing)	This involves use of a lancet device to prick the finger and draw a drop of blood. A testing strip is used to absorb the blood sample and deliver a blood glucose result via insertion into a glucometer. Adjunctive: Some CGM devices recommend testing capillary blood glucose to support treatment decisions, including insulin dose decisions. Device labels may additionally require capillary blood glucose checking for symptoms of hypoglycaemia and some devices also require regular capillary blood glucose testing to calibrate the CGM device. These devices will require an additional regular FP10 prescription of capillary blood glucose testing strips and lancets.

	Non-adjunctive: This is a CGM device which states that additional capillary blood glucose testing is not required to make treatment decisions.
Hybrid closed loop	Hybrid closed-loop technology involves both a CGM and CSII device. The CSII device uses an algorithm to continuously take glucose readings from a CGM device and calculate how much background insulin is needed. It then automatically delivers the insulin via pump. The device therefore automatically adjusts the background insulin delivery if glucose levels go too low or high. With a hybrid-closed loop device, the individual must still control how much bolus insulin is given.
Low glucose alerts	A Continuous Glucose Monitoring device that alerts the sensor wearer when their blood glucose level drops below a certain figure. The aim is to prevent a hypoglycaemic or severe hypoglycaemic episode, depending on the figure that the alert is set to. All CGM devices offer low glucose alerts as a feature, and the level they are set at can be altered according to individual preference and clinical need. Optional low glucose alert - These alerts can be turned off if the individual/clinician prefers or recommends this. Mandatory low glucose alerts - These low glucose alerts operate at a fixed blood glucose level and cannot be silenced or turned off. They are aimed at preventing blood glucose falling to dangerously low levels. Predictive low glucose alerts - These offer advance warning alerts of when a low blood glucose level will occur, so that preventative action can be taken. They may be fixed or optional.
High glucose alerts	As per low glucose alerts above. High glucose alerts are usually optional and/or predictive, and rarely fixed.
Gold score	A linear assessment scale to assess awareness of hypoglycaemia symptoms. Regularly completed in specialty type 1 diabetes centres to assess the level of awareness an individual has of their hypoglycaemic episodes.