# *A pan-London implementation document for continuous glucose sensors for children and young people (CYP) with Type 1 diabetes: written pathway*

Version 1.0

Circulated date: January 2024

Date agreed at LCEG: December 2023

Review date: July 2024

*This document will be reviewed and re-released to reflect new and emerging evidence as appropriate. Please email england.cyptransformationldn@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 children and young people (CYP) with type 1 diabetes

## Scope and rationale:

The National Institute for Health and Care Excellence (NICE) Guidance for children and young people (CYP) with type 1 diabetes (T1DM) NG18 changed in 2022 to include access to continuous glucose monitoring (CGM) technologies for all CYP living with the condition[1]. This is an implementation document which aims to support NG18, empowering informed choice of device for CYP with T1DM and their families and carers, 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 CYP with T1DM only. A companion implementation document is also available for CGM access for adults living with T1DM. This document does not cover the use of CGM in CYP with hypoglycaemia arising from other causes for whom funding requests for CGM should be made through the Individual Funding Request mechanism.

A full cost effectiveness evaluation of the expansion of access to CGM was undertaken as part of the NICE guidance development process. The NICE guidelines also include a local resource impact template. This is mainly adult focused. To provide a better overview for each ICB we have obtained the 2021-2022 National Paediatric Diabetes Audit data with a breakdown of CGM and intermittent scanned usage for each ICB. This information is contained within separate documents available on request.

When choosing a CGM 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
- Accompanying device list

Devices included as part of the pan-London documentation have been selected based on accuracy in children and young people. Further information can be found in the device list.

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

## 1. Who should start Continuous Glucose Monitoring in CYP

CGM should be offered to all children and young people with T1DM. For newly diagnosed children and young people, this should be offered at the point of diagnosis as part of routine diabetes management.

CGM should be provided by a Paediatric Diabetes team with expertise in its use and interpretation of the data generated, as part of supporting CYP to self-manage their diabetes.

The initiation of all types of CGM within paediatric practice is the responsibility of the paediatric diabetes team. Ongoing supply of sensors will depend on the type of CGM provided to the CYP with Type 1 Diabetes.

NICE (NG18) Guidance on use of CGM was published prior to the changes to the Freestyle Libre (also known as Flash) systems. Please refer to the Devices list for current information on type of CGM and current licensed age for use.

CYP under the age of 2 years have the greatest need for CGM and off license use will be guided and supported by the clinical team.

## 2. What type of Continuous Glucose Monitoring should be offered to CYP with T1DM

a) First line

Offer rtCGM to all CYP with T1DM, alongside education to support CYP and their families and carers to use it.

b) Second line

Offer isCGM, (commonly referred to as 'flash') to CYP with T1DM aged 4 years and over who are unable to use rtCGM or who express a clear preference for isCGM.

c) Third line

If a person cannot use or does not want rtCGM or isCGM, offer capillary blood glucose monitoring.

Please note, capillary blood glucose testing will be required alongside CGM for CYP with T1DM. This is 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. Further details can be found in the device list.

## 3. Deciding on a device with the individual with T1DM

When offering CYP with T1DM a choice of rtCGM device it should be based on their individual preferences, needs, characteristics, and the functionality and accuracy of the devices available. The following should be considered:

- Accuracy of the device. The accuracy of the device particularly in the hypoglycaemic range should be assessed using paediatric specific data. It is recommended that only devices which have paediatric specific data supporting the product licence should be used. Accuracy data should include both MARD and 15/15 agreement rates [2]. Definitions provided in Appendix 1.

- Whether the device provides predictive alerts or alarms and if these need to be shared with anyone else, for example a parent or carer[1].

- Whether using the device requires access to technologies (such as a smartphone and up-to-date phone software).

- Whether a patient has a compatible smartphone and working email address.

- Any additional health and/or care needs.

- How easy the device is to use and take readings from, including for people with limited dexterity (taking into account the age and abilities of the CYP and also whether the device needs to be used by others).

- Fear, frequency, awareness, and severity of hypoglycaemia.

- Psychosocial factors.

- The CYP's insulin regimen or type of insulin pump. Take into account whether a particular device integrates with their pump as part of a hybrid closed loop or insulin suspend function.

- Calibration requirements Consider the impact of calibration requirements for a device.

    - Calibration may be required/beneficial for use of a sensor with a Hybrid Closed Loop system.

    - If calibration is required, what is the level of burden (number of calibrations per day) and how easy it is for the person to do this themselves.

- How data can be collected, compatibility of the device with other technology, and whether data can be shared with the person's healthcare provider to help inform treatment.

- How unpredictable the CYP's activity and blood glucose levels are and whether erratic blood glucose is affecting their quality of life.

- Whether the choice of device will impact on the CYP's ability to attend school or education, or to do their job.

- Whether the CYP takes part in sports or exercise when glucose levels will need additional management.

- Whether the CYP has situations when symptoms of hypoglycaemia cannot be communicated or can be confused, for example during exercise.
- Clinical factors that may make devices easier or harder to use.
- Frequency of sensor replacement. pat
- Sensitivities to the device, for example local skin reactions.
- Body image concerns.
- The cost of a device. If multiple devices meet an individual's needs and preferences, offer the device with the lowest cost.

## 4. Monitoring and Stopping Rules for the use of Continuous Glucose Monitoring

Include CGM in the continuing programme of education provided to all CYP with T1DM and their families or carers.

Monitor and review the CYP's use of CGM as part of reviewing their diabetes care plan and explain to them the importance of continuously wearing the device.

If the CYP is not using their CGM device at least 70% of the time (80% if on hybrid closed loop system):

a. Ask if they are having problems with their device and assess other factors that may impact on device use including psychosocial barriers and parental/carer specific factors.

b. Look at ways to address any problems or concerns to improve use of the device, including further education and emotional and psychological support.

c. Advise on risk of undetected hypoglycaemia.

d. Offer additional support to a family or carer if required.

**Stop/change system if following on from additional support:**

a. Wear of the CGM is not 70% or greater (80% if on hybrid closed loop system) **and** there are no patient or parent/carer reported benefits.

   Patient benefits that would support ongoing use of CGM where wear is less than 70% include but are not limited to HbA1c reduction, reduced hypoglycaemia rates and hypoglycaemia fear, reduction in admission rates psychosocial benefits, increased confidence, increased education attendance and improved sleep.

Parent/carer benefits may include (but are not limited to) improved sleep, decreased worry, decreased hypoglycaemia fear.

Clinical judgement should be used to support improving outcomes for those with very low (less than 30%) sensor wear.

b. There are skin reactions not amenable to standard interventions.

c. The CYP does not wish to continue with the system.

## References


1. Diabetes (type 1 and type 2) in children and young people: diagnosis and management (2023) NICE guideline NG18

2. Pemberton JS, Wilmot EG, Barnard-Kelly K, et al. CGM accuracy: Contrasting CE marking with the governmental controls of the USA (FDA) and Australia (TGA): A narrative review. Diabetes Obes Metab.2023;1-24. doi:10.1111/dom.14962

# Appendix 1: Clinical Terms and acronyms

Acronyms in this implementation document have been used in line with those in the NICE NG18 to provide consistency.

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| CGM | Continuous Glucose Monitoring<br><br>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<br><br>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<br><br>Also known as ‘flash’ glucose monitoring.<br>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<br><br>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 blood testing strip is used to absorb the blood sample and deliver a blood glucose result via insertion into a glucometer.<br><br>Adjunctive:<br>Some CGM devices recommend checking 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 checks to calibrate the CGM device.<br><br>These devices will require an additional regular primary care FP10 prescription of capillary blood glucose testing strips and lancets.<br><br>Non-adjunctive: |

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| | This is a CGM device which states that additional capillary blood glucose checks are not required to make treatment decisions. |
| Hybrid closed loop | Hybrid closed-loop technology involves both a CGM and CSII device.<br><br>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.<br>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.<br><br>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.<br><br>Optional low glucose alert<br>- These alerts can be turned off if the individual/clinician prefers or recommends this.<br><br>Mandatory low glucose alerts<br>- 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.<br><br>Predictive low glucose alerts<br>- 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.<br>High glucose alerts are usually optional and/or predictive, and rarely fixed. |
| Clarke hypoglycaemia score | A linear assessment scale to assess awareness of hypoglycaemia symptoms.<br>May be completed in specialty type 1 diabetes centres to assess the level of awareness an individual has of their hypoglycaemic episodes. There are limitations to the score as it has not been modified for use with HCL systems |
| MARD | Mean Absolute Relative Difference, a measure of accuracy of CGM devices and blood glucose meters. MARD is a |

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| | measure of the difference between the CGM value and a reference blood glucose measurement[1] |
| 15/15 agreement rates | Percentage of CGM values falling within specified limits of the corresponding reference values. See Pemberton et al 2022 for full explanation |

[1]Reiterer F, Polterauer P, Schoemaker M, Schmelzeisen-Redecker G, Freckmann G, Heinemann L, Del Re L. Significance and Reliability of MARD for the Accuracy of CGM Systems. J Diabetes Sci Technol. 2017 Jan;11(1):59-67. doi: 10.1177/1932296816662047. Epub 2016 Sep 25. PMID: 27566735; PMCID: PMC5375072.