**Continuous Glucose Monitoring Device choice recommendations in Adults, Children and Young People with Type 2 Diabetes**

1. **Factors in choice of CGM device**

NICE recommend a list of factors to consider when choosing a CGM device 1,2:

*Factors to consider when choosing a continuous glucose monitoring device:*

*• Accuracy of the device*

*• Whether the device provides predictive alerts or alarms and if these need to be shared with anyone else (for example, a parent or carer)*

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

*• How easy the device is to use and take readings from, including for people with limited dexterity (for children and young people: taking into account the age and abilities of the child or young person and also whether the device needs to be used by others)*

*• Fear, frequency, awareness, and severity of hypoglycaemia*

*• Psychosocial factors*

*• The person's insulin regimen if they are using insulin*

*• Whether, how often, and how the device needs to be calibrated, 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*

*• Whether the device will affect the person's ability to do their job. For children and young people: Whether the choice of device will impact on the child or young person's ability to attend school or education.*

*• How unpredictable the person's activity and blood glucose levels are and whether erratic blood glucose is affecting their quality of life*

*• Whether the person has situations when symptoms of hypoglycaemia cannot be communicated or can be confused (for example, during exercise)*

*• For children and young people: Whether the child or young person takes part in sports or exercise when glucose levels will need additional management*

*• Clinical factors that may make devices easier or harder to use*

*• Frequency of sensor replacement*

*• Sensitivities to the device, for example local skin reactions*

* *Whether the CGM is real-time or intermittent CGM is required.*

*• Body image concerns*

NICE recommend that if multiple devices meet a person’s needs and preference, **the device with the lowest cost should be offered**.

A summary table of features of different CGM devices available, their cost and current Traffic Light Status in Surrey Heartlands is attached.

1. **Considerations for choice of CGM device**

The annual cost of CGM devices varies considerably depending on the features of the device. The most cost-effective devices are easily available on FP10 prescription and cost ~£900 per year (£778/year for GlucoRx Aidex). CGM devices vary in their accuracy, licensing for non-adjunctive use to dose insulin, licensing for use in children, data sharing functions (with carers and health care professionals), low glucose alerts and compatibility for use with an insulin pump, as part of a closed loop system.

Considerations for CGM choice should take into account features of the device and needs of the patient (data sharing, low glucose alarms). Recommendations are made on cost-effective choices of CGM device that meet patient needs.

The range of CGM devices available to the NHS is rapidly changing as the market for CGM becomes more competitive. This often results in more cost-effective choices becoming available. Regular horizon scanning and review of the CGM products available, and updated features in current products is recommended to ensure Surrey Heartlands benefits from the most cost-effective CGM device choices.

Device accuracy:

NICE note that a key factor in choice of device is accuracy, although no guidance is given on how device accuracy should be assessed. All devices marketed in the UK have a CE marking, which means they meet certain essential requirements of the European Commission. However, the CE marking is not a reliable marker for the accuracy and performance of CGM devices3. This contrasts with pharmaceuticals which must undergo rigorous testing and clinical trials before being licensed.

Pemberton et al3 refer to a study whereby more than 80% of people used a GlucoRx Aidex and had type 2 diabetes. No glucose variability was induced and during the study visits only 1% of readings were time below range <3.9mmols/l. They also identified that there is no publicly available clinical data for GlucoMen Day, GlucoRx Aidex and TouchCare Nano in children.

1. **CGM device choice recommendations**

Table below provides recommended traffic light status and short rationale for recommendation.

|  |  |  |
| --- | --- | --- |
| **CGM Device** | **Current / Proposed TLS** | **Rationale** |
| *Listed in Drug Tariff for FP10 prescribing* | | |
| Freestyle Libre 2 | Proposed TLS = Blue | * Cost-effective- lowest cost * No accuracy concerns * Data sharing possible (carer and HCP) * Note- now is a rtCGM if used with a smartphone- this has better outcomes than isCGM1,2. * **Can use in children from age 4** |
| Dexcom One | Proposed TLS = Blue | * Cost-effective- lowest cost * No accuracy concerns. * rtCGM * No data sharing possible. * **Can use in children from age 2** |
| GlucoRx Aidex | Proposed TLS = Non-formulary | * Not licensed for insulin dosing (non-adjunctive use) * Requires the user to verify their sensor glucose level with a capillary blood glucose test before insulin bolus for a meal. This adds to the diabetes burden for the patient and increases the CGM cost for capillary glucose test strips. * **Accuracy concerns** |
| **CGM Device** | **Current / Proposed TLS** | **Rationale** |
| *Hospital only CGM* | | |
| A8 Touchcare Nano | Proposed TLS = non-formulary | * Accuracy concerns * No publicly available data in children * Requires calibration |
| Freestyle Libre 3 | Proposed TLS = RED hospital only. | * Cost-effective – lower cost but less cost-effective than Freestyle Libre 2 * hospital only CGM. * No accuracy concerns * Data sharing possible (carer and HCP) * Can use in children from age 4 * No predictive low alert |
| Dexcom G7 | Proposed TLS = RED , hospital only | * **Moderate cost** * No accuracy concerns * Data sharing possible (carer and HCP) * **Can use in children from age 2.** * **Predictive low glucose alert** |
| Dexcom G6 | Proposed TLS = non-formulary | * Expensive- high cost * No accuracy concerns * Data sharing possible (carer and HCP) * Can use in children from age 2 * Predictive low glucose alert |
| Medtronic Guardian 3 | Proposed TLS = non-formulary | * Expensive – high cost * Data sharing possible (carer and HCP) * Can use in children any age * Predictive low glucose alert - optional |
| Medtronic Guardian 4 | Proposed TLS = non-formulary | * Expensive -high cost * Data sharing possible (carer and HCP) * Can use in children from aged 7 * Predictive low glucose alert - optional |

|  |  |
| --- | --- |
| **Hospital only CGM** | |
| Dexcom 6 | £3,174 |
| Guardian 3 & 4 | £3,170 |
| Dexcom 7 | £2,214 |
| Freestyle Libre 3 | £1,121 |
| A8 Touchcare Nano | £1,110 |

|  |  |
| --- | --- |
| **FP10 prescribed CGM** | |
| Dexcom One | £912 |
| Freestyle Libre 2 | £912 |

Patients with Type 2 diabetes do not have the risks for severe hypoglycaemia as those with type 1 diabetes. Therefore, the need for predictive low glucose alert is not necessary unless a patient is young and cannot communicate that they are experiencing signs and symptoms of a hypoglycaemic attack.

NICE recommend that if multiple devices meet a person’s needs and preference, the device with the lowest cost should be offered.

The hospital only CGM devices are more costly than those that are available on FP10 so should not be the first-line choice of CGM for CYP with T2DM and are recommended to be non-formulary for this group of people.

There are three CGM devices currently available on FP10:

* **GlucoRx Aidex:** there are accuracy concerns for this CGM, so it is proposed that this is non -formulary
* **Freestyle Libre 2:** is an intermittently scanned continuous glucose monitoring system currently available (isCGM) **if using a reader**. **However, if using a smartphone, then it can be used as a real time continuous glucose monitoring system (rtCGM).** It is cost effective and easy to use. It is recommended for use in adults and children above **4 years of age**. Data from the device can be shared with the person’s healthcare professional (HCP) and family/carers.
* **Dexcom One:** is a real time CGM device for adults and children from the age of **2 years.** The transmitter and sensor are both available on FP10. The data from this device **cannot be shared** with their HCP.

**Hospital only CGM:**

* **Dexcom G7**: The devices above do not have any predictive low glucose alert. This may be required by those patients who are young and cannot communicate to their carers/parents that they are having a hypoglycaemic episode. The use of Dexcom G7, the most cost-effective CGM with this functionality, is proposed for this cohort of patients. It is also, the only CGM that is cost-effective and licensed for use in children above 2 years. (Although it is extremely rare to have a patient with type 2 diabetes who is so young.)

Patient education to initiate Dexcom One and Freestyle Libre 2 is clear, succinct, and available online.

CYP with T2DM are managed by secondary care specialist diabetes teams and can be initiated and managed by these teams. Therefore, it is proposed that **Dexcom One, Freestyle Libre 2**, CGM devices should be available for use in CYP with T2DM and have a BLUE traffic light status as they can be prescribed on FP10.  **Freestyle Libre 3, and Dexcom G7** CGM should also be made available and have a RED hospital only traffic light status as they cannot be prescribed on FP10.

***Transition to adult services:***

T2DM in CYP compared to adults demonstrate unique features such as a rapid decline in β cell function and accelerated development of diabetes complications4.

CYP onset T2DM has become more common, carries a high disease burden, and is associated with increased short term and long-term morbidity.

This underscores the critical significance of swift intervention and proactive diabetes management immediately following diagnosis. The availability of Continuous Glucose Monitoring (CGM) equips CYP with T2DM with essential resources for self-care, enabling them to effectively navigate diabetes management and curtail the risk of complications. Recognising that these youths will contend with diabetes over an extended period, it is recommended that their access to CGM be sustained as they transition into adult services.

***Self-funding patients:***

Prior to publication of NG17 and NG18, some patients with type 2 diabetes have been self-funding their CGM. In line with our Surrey Heartlands [guidelines](https://surreyccg.res-systems.net/PAD/Guidelines/Detail/4410) on NHS prescribing following a private episode of care, these patients should be offered CGM in line with our cost-effective choices and pathway.

**References**:

1. 2022 NICE Type 1 diabetes in adults: diagnosis and management. NG17. Available at <https://www.nice.org.uk/guidance/ng17>. Accessed 11th August 2023.
2. 2022 NICE Diabetes (type 1 and type 2) in children and young people: diagnosis and management. NG18. Available at <https://www.nice.org.uk/guidance/ng18>. Accessed 11th August 2023.
3. Pemberton 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: 25:916-939. Accessed 11th August 2023.
4. American Diabetes Association; 12. Children and Adolescents: Standards of Medical Care in Diabetes—2018. Diabetes Care 1 January 2018; 41 (Supplement\_1): S126–S136. <https://doi.org/10.2337/dc18-S012> Accessed 11th August 2023.