Continuous Glucose Monitoring Device choice recommendations in Adults, Children and Young People with Type 1 Diabetes and Pregnant Women with gestational 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 or type of insulin pump, if relevant (taking into account whether a particular device integrates with their pump as part of a hybrid closed loop or insulin suspend function)*
- *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*
- *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 as paper 7.

2. 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 **REDACTED** per year (**REDACTED**/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.

The more sophisticated CGM devices that include full alarm functionality, data sharing options and can be used as a closed loop system with an insulin pump have the highest annual cost of **REDACTED** per year. Not all patients requiring CGM require all the features of the most expensive CGM devices, therefore based on features of the device and needs of the patient (data sharing, low glucose alarms and insulin pump compatibility) 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 devices[3]. This is in contrast to pharmaceuticals which have to undergo rigorous testing and clinical trials before being licensed.

Pemberton et al[3] refer to a study whereby more than 80% of people used a GlucoRx Aidex but 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, therefore the study performance criteria against the CGM standards for type 1 diabetes is not meaningful. The review also notes there are sparse study results of the performance of GlucoRx Aidex and Medtrum Touchcare Nano in the type 1 diabetes population. These studies omit glucose and insulin challenges and are not representative of the typical glucose excursions experienced by the Type 1 population. They also identified that there is no publicly available clinical data for GlucoMen Day, GlucoRx Aidex and TouchCare Nano in children.

3. 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	Current TLS = Blue No change proposed	• Cost-effective • No accuracy concerns • Data sharing possible (carer and HCP) • Can use in children from age 4
Dexcom One	Proposed TLS = Blue	• Cost-effective • No accuracy concerns • 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 and limited data in T1DM
Glucomen Day	Proposed TLS = Non-formulary	• Accuracy concerns • No publicly available data in children • Company will no longer be supporting initiations in new patients in UK
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	Current TLS = Red No change proposed	• Cost-effective • No accuracy concerns • Data sharing possible (carer and HCP) • Can use in children from age 4 • But no predictive low alert, and not currently compatible with closed loop insulin system
Dexcom G7	Current TLS = Red No change proposed	• Moderate cost • No accuracy concerns

		• Data sharing possible (carer and HCP) • Can use in children from age 2 • Predictive low glucose alert • Not currently compatible with closed loop insulin system
Dexcom G6	Current TLS = Red No change proposed	• Expensive • No accuracy concerns • Data sharing possible (carer and HCP) • Can use in children from age 2 • Predictive low glucose alert • Compatible with closed loop insulin system
Medtronic Guardian 3	Current TLS = Red No change proposed	• Expensive • Data sharing possible (carer and HCP) • Can use in children any age • Predictive low glucose alert - optional • Compatible with insulin pump 640G
Medtronic Guardian 4	Current TLS = Red No change proposed	• Expensive • Data sharing possible (carer and HCP) • Can use in children from aged 7 • Predictive low glucose alert - optional • Compatible with insulin pump 780G

4. CGM devices recommended for FP10 prescribing.

Current APC policy requires detailed initiation and continuation forms be provided by diabetes teams to the patients GP to enable prescribing of Freestyle Libre 2 in primary care. This is seen as a considerable work burden by diabetes teams, although provided assurance that the patient met the previous NHS England criteria for funding of Freestyle Libre 2. Updated national guidance has widened the patient groups who can be offered CGM and reduces the need for detailed assurance that the patient meets criteria for Freestyle Libre 2.

To align with their Blue traffic light status, it is recommended that a Blue information sheet replaces the current initiation and continuation communication forms on Surrey PAD for both Freestyle Libre 2 and Dexcom One. A proposed blue information sheet, and suggested communication template is attached as Appendix N.

Dexcom One is a recommended real time CGM device for adults and children from the age of 2 years. Similarly, to Freestyle Libre 2 it is cost effective and easy to use. Patient education to initiate Dexcom One is clear, succinct and available online. The transmitter and sensor are

both available on FP10. Dexcom One meets the integrated CGM accuracy performance standards are for adults and paediatrics, as it uses the same sensor and algorithm as the Dexcom G6[3].

5. Pathway and cost-effective choice of CGM

To ensure the most appropriate and cost-effective CGM devices are used to meet patient needs, flow charts to aid decision making with accompanying table of CGM choices have been developed for the following patient groups:

- Adults with Type 1 diabetes and pregnant women (attached) Appendix L
- Children and Young People with Type 1 diabetes. (attached) Appendix M

Problematic Hypoglycaemia – defined in the pathways as two or more episodes of severe hypoglycaemia a year or as one episode associated with impaired awareness of hypoglycaemia. This also includes patients expressing a major fear with maladaptive behaviour. Choudhary et al[4]. NICE[2] recommend a review of causes of hypoglycaemia if it becomes unusually problematic or increases in frequency.

Self-funding patients:
Prior to publication of NG17 and NG18, some patients with type 1 diabetes have been self-funding their rtCGM (often Dexcom 6). In line with our Surrey Heartlands guidelines on NHS prescribing following a private episode of care, these patients should be offered CGM in line with our cost-effective choices and pathway.

6. Management and assurance of spend on CGM

Hospital only CGM are National Tariff Payment System excluded devices that currently require notification to the ICB that a patient has been initiated and meets current funding criteria using the Blueteq® system. Some of our Trusts are unable to provide timely and accurate information on which CGM devices are used and level of expenditure, therefore it is recommended that the Blueteq® system is continued to notify the ICB Medicines Resource Unit of CGM initiation, albeit with a simplified form and without the need for a continuation form. This would be a notification not a request for funding, but allows some oversight of CGM usage alongside primary care prescribing data on CGM usage.

It is recommended that a notification using the Blueteq® system is made to alert the ICB when CGM is stopped, or when the patient leaves the area.

References:

1. 2022 NICE Type 1 diabetes in adults: diagnosis and management. NG17. Available at https://www.nice.org.uk/guidance/ng17. Accessed 28th February 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 28th February 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.

4. Choudhary,P, Rickels,M, Senior,P, Vantghem MC, Maffi P,Kay T,Keymeulen B,Inagaki N, Saudek F, Lehmann R, Hering B. Evidence-Informed Clinical Practice Recommendations for Treatment of Type 1 Diabetes Complicated by Problematic Hypoglycemia. Diabetes Care.2015; 38(6):1016-1029