NHS
Nottingham and Nottinghamshire

Implementing a Continuous Glucose Monitoring (CGM) Formulary for Nottingham and Nottinghamshire

1. Background

Studies (see appendix for details of some of the studies) have shown that CGM technology reduces HbA1c, hypoglycaemia admissions, DKA admissions and the occurrence of major complications for those living with Diabetes.

In Nottingham and Nottinghamshire we have a policy for flash glucose monitors (Freestyle Libre®) but no policy for CGM. Our current flash glucose monitoring policy meets the new NICE guidance released in March 2022 which recommends access to isCGM or rtCGM (see appendix for explanations of these terms) devices for all Type 1 patients and certain cohorts of Type 2 patients.

NHSE issued the following statement on 2nd August 2022 "NHS England patients with Type 1 diabetes will now be eligible for life-changing continuous glucose monitors after the health service secured a new cut-price deal".

This statement from NHSE combined with the new NICE guidance and a wider availability of devices on the market supports the need to review our local Nottingham and Nottinghamshire APC Formulary and policy in relation to both isCGM and rtCGM to ensure that we have suitable options for our patients in Nottingham and Nottinghamshire.

Aim

To review all available CGM devices (as @ July 2022) against local agreed criteria to ensure that the most suitable devices are included within our local Nottingham and Nottinghamshire APC formulary choices

Where the essential criteria are met, we will look at ensuring that we have options available for a wide range of purposes and needs and that clinicians are directed to the most cost-effective options where appropriate

2. Methodology

A Nottingham and Nottinghamshire task and finish group comprising of secondary and primary care specialists, interface pharmacist and ICB senior pharmacists met to agree a list of questions for device manufacturers and to agree the essential criteria for devices.

In Nottingham and Nottinghamshire we have decided on a 2-level option appraisal. Our agreed essential criteria forms level 1 as below

	Criteria Level 1 - applies to all devices	Agreed
Technical Info	Is the device approved for Non-adjunctive use?	Essential
Technical Info	Does this device have alarms for High and Low readings?	Essential
Technical Info	Does the device allow data sharing with HCPs	Essential
Technical Info	Which platforms can data be shared with?	Essential
Technical Info	Is the server GDPR Compliant?	Essential
Other Information	Is training available for HCPs for this device?	Essential
Other Information	Would training be available to community pharmacies for this device?	Essential
Other Information	Is training available for patients for this device?	Essential
Other Information	Is a helpline available for patients?	Essential

Once level 1 is complete a further set of criteria will be applied to ensure that we have a range of devices suitable for our local population and prescribing in both primary and secondary care settings. Our level 2 criteria are below.

	Criteria Level 2 - Once Level 1 complete Level 2 will ensure that we have all needs covered	Agreed
Basic Info	What ages and groups is this device licenced for?	Both
Basic Info	Is this a REAL TIME device?	Both
Technical Info	Is a reader available from the manufacturer? (if required)	Both
Technical Info	Can the sensors for this product be prescribed on an FP10?	Both
Technical Info	Is this device compatible with any pumps?	Both
Technical Info	Which pumps is the device compatible with?	Both
Technical Info	Is the device compatible with closed loop?	Both
Technical Info	Are real time data sharing with alerts possible?	Both
Technical Info	Is the device appropriate for those who are visual impairment?	Both
Technical Info	Is the device appropriate for those with a hearing impairment?	Both
Other Information	Are patient facing materials available in easy to read formats or alternative formats for patients with learning diabilities?	Both
Technical Info	Does the device have IOS/ android compatibility	Both
Technical Info	Does the device need a reader?	Both

An email was sent to each manufacturer with a device currently on the market with a link to an online questionnaire containing a list of 54 questions. The completion deadline date was Friday 15th July 2022 and no after date submissions or information sent outside the questionnaire has been included in this options appraisal. A copy of the questionnaire can be found in the appendix.

Information has now been collated and a full copy of the collated data set can be found in the appendix.

The same process is being undertaken across the Midlands Region in the hope of standardising the range of products available but local Area Prescribing Committees will be reviewing the options independently using their own agreed criteria.

3. Options appraisal process and outcomes

Level 1 criteria outcome

Essential Level 1 Criteria agreed in LLR		Device 1	Device 2	Device 3	Device 4	Device 5	Device 6	Device 7	Device 8	Device 9	Device 10	Device 11
Is the device approved for Non-adjunctive use?	Essential	No	Yes	Yes	Yes	No	Yes	Yes	Yes	Yes	Yes	Yes
Does this device have alarms for High readings?	Essential	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Does this device have alarms for Low readings?	Essential	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Does the device allow data sharing with HCPs	Essential	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Is the server GDPR Compliant?	Essential	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Is training available for HCPs for this device?	Essential	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Is training available for patients for this device?	Essential	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Would training be available to community pharmacies for this device?	Essential	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Is there a helpline available for patients using this device?	Essential	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes

Device 1 (GlucoRX AiDEX) and Device 5 (Guardian™ Connect EE Transmitter Starter Kit) did not meet the non-adjunctive use criteria and therefore we have removed them from the second stage of our process.

In summary the following devices all met the level 1 essential criteria:

- A8 TouchCare Nano® CGM
- FreeStyle Libre 3® Continuous Glucose Monitoring System
- FreeStyle Libre 2® Glucose Monitoring System
- Guardian™ 3 Link Starter Kit
- Guardian™ 4 Link Starter Kit
- Dexcom One®
- Dexcom G6®
- Dexcom G7®
- GlucoMen Day® CGM

Level 2 Assessment Criteria

Level 2 criteria for each of the products meetings level 1 essential criteria can be found below

Level 2 LLR Criteria	Device 2	Device 3	Device 4	Device 6	Device 7	Device 8	Device 9	Device 10	Device 11
	A8 TouchCare Nano CGM	FreeStyle Libre 3 Continuous Glucose Monitoring System	FreeStyle Libre 2 Glucose Monitoring System	Guardian™ 3 Link Starter Kit	Guardian™ 4 Link Starter Kit	Dexcom One	Dexcom G6	Dexcom G7	GlucoMen Day CGM
What ages and groups is this device licenced for?	2 years and above	age 4 and older	age 4 and older	does not have age restrictions	7 y.o. and above	Age 2 upwards	Age 2 upwards	Age 2 upwards	Adults, Children (6+), pregnant women, people on dialysis, and people who are critically ill.
Is this a REAL TIME device?	Yes	Yes	No	Yes	Yes	Yes	Yes	Yes	Yes
Is a reader available from the manufacturer? (if required)	Yes	No	Yes	Not applicable - not required	Not applicable - not required	Yes	Yes	Yes	Yes
Can the sensors for this product be prescribed on an FP10?	No	No	Yes	No	No	Yes	No	No	Yes
What platforms can data be shared with?	Medtrum EasyView Pro website	LibreView The LibreLinkUp app can be used by third parties, for example family members or caregivers, to access glucose data stored in LibreView, and alarms issued by the FreeStyle Libre3 app.	LibreView The LibreLinkUp app can be used by third parties, for example family members or caregivers, to access glucose data stored in LibreView, and alarms issued by the FreeStyle LibreLink app.	CareLink™	CareLink™	Clarity, Diasend/ Glooko,, Tidepool	Clarity, Diasend/ Glooko, Tidepool	Clarity, Diasend/ Glooko, Tidepool	Diasend and GlucoLog Web
Does the device have IOS/ android compatibility	IOS & ANDROID	ANDROID but IOS is coming	IOS & ANDROID	IOS & ANDROID	IOS & ANDROID	IOS & ANDROID	IOS & ANDROID	IOS & ANDROID	IOS
Is this device compatible with any pumps?	Yes	No	No	Yes	Yes	No	Yes	Yes	Yes
Which pumps is the device compatible with?	Medtrum A8 TouchCare Nano Patch Pump	Partnerships are in place with Insulet, Tandem, Ypsomed. Will update as more information becomes available.	N/A	MiniMed™ 640G, MiniMed™ 670G	MiniMed™ 780G	N/A	Tandem, Omnipod, Ypsomed, Cam APS, Diabeloop	Pump compatibility TBC	In relation to question 23 & 25, compatiblity with several pumps via Diabeloop is expected later this year.
Is the device compatible with closed loop?	Yes	No	No	Yes	Yes	No	Yes	No	Yes
Are real time data sharing with alerts possible?	Yes	Yes	No	Yes	Yes	No	Yes	Yes	Yes
Is the device appropriate for those who are visual impairment?	Yes	Yes	Yes	No	No	Yes	Yes	Yes	Yes
Is the device appropriate for those with a hearing impairment?	Yes	Yes	Yes	No	No	Yes	Yes	Yes	Yes
Are patient facing materials available in easy to read formats or alternative formats for patients with learning diabilities?	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes

4. The NICE Recommendations

When considering the options to include on the formulary we need to consider the NICE recommendations for CGM published in April 2022 for people living with Type 1 diabetes (NG17), Type 2 diabetes (NG28) and children and young adults with diabetes (NG18). Guidance also exists for pregnant women (NG3). NHSE advise that all Integrated Care Systems implement these guidelines, offering the technology to all eligible patients, given the evidence base which strongly supports the benefits to patient outcomes.

A note on making decisions using NICE guidelines
www.nice.org.uk/about/what-we-do/our-programmes/nice-guidance/nice-guidelines/making-decisions-using-nice-guidelines
Some recommendations are made with more certainty than others

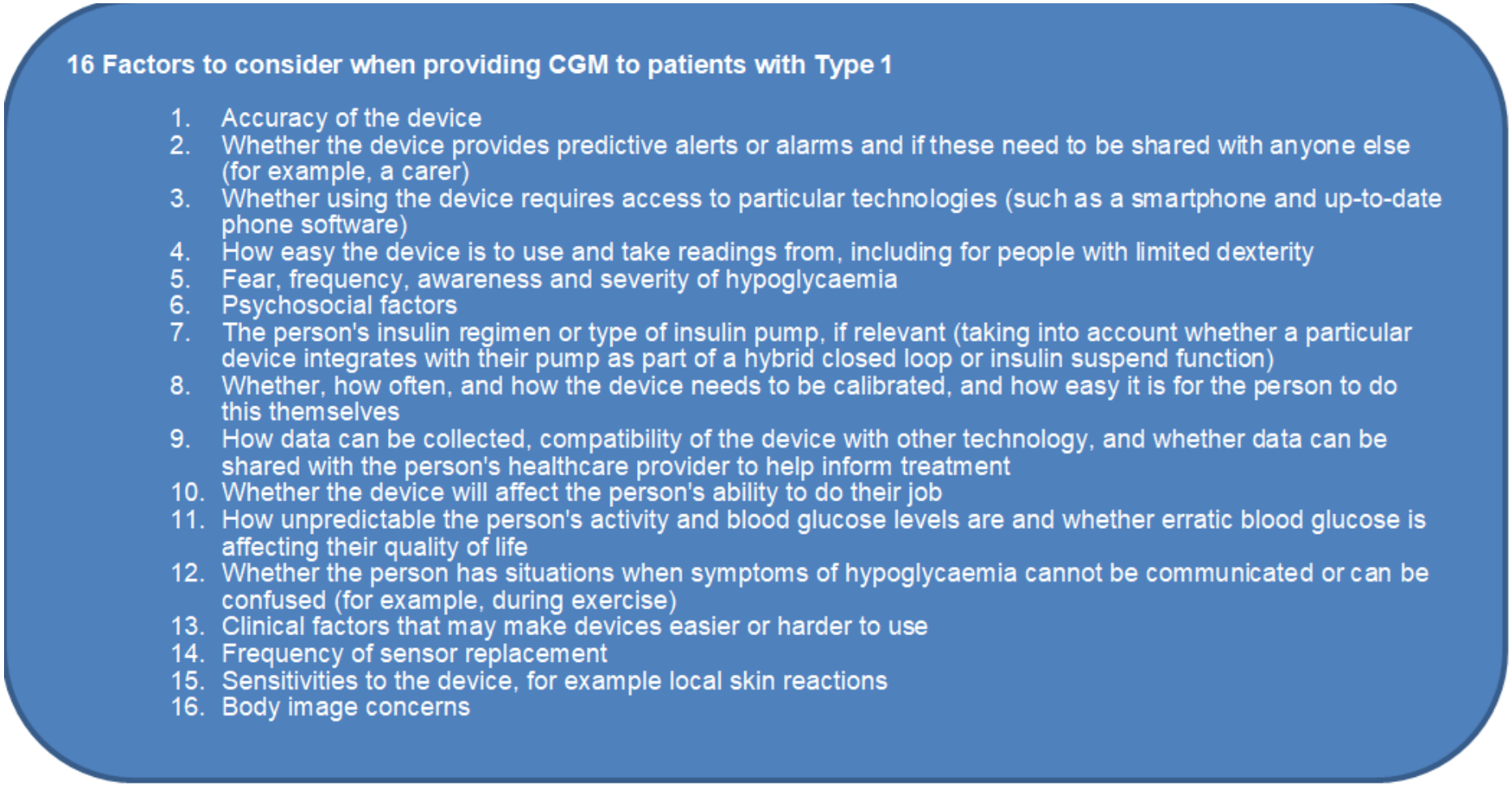
- Where there is clear and strong evidence of benefit, we use the word **'offer'**
- Where the benefit is less certain we use the word **'consider'**

Useful terminology in relation to CGM

- **Continuous glucose monitoring (CGM)** – systems that track glucose levels through a sensor inserted under the skin of the abdomen or arm. CGM can be used with or without an insulin pump. There are 2 types:
    - Real time CGM (rtCGM) – sensor tracks glucose levels throughout the day & night; some can alert if levels go too high/low. Results sent to receiver or smart device. (Examples include Dexacom G6, GluoMen Day, Guardian Connect, GlucoRx Aidex)
    - Intermittently scanned CGM (isCGM or flash CGM) – sensor does not automatically send readings, users swipe the receiver or smartphone over it to get readings. (Examples include FreeStyle Libre)
- **Self-monitoring of blood glucose (SMBG) – intermittent finger prick testing using test strips**

NG17 Type 1 diabetes: https://www.nice.org.uk/guidance/ng17

- **Offer** adults with type 1 diabetes a choice of real-time continuous glucose monitoring (rtCGM) or intermittently scanned continuous glucose monitoring (isCGM, commonly referred to as 'flash'), based on their individual preferences, needs, characteristics, and the functionality of the devices available. NICE lists 16 factors which need to be considered when choosing a device: therefore, choice of device to suit an individual's needs is of paramount importance. A list of the 16 factors can be found below



- The advice of NICE when choosing a CGM device is to use shared decision making to identify the person's needs and preferences, and offer them an appropriate device, if multiple devices meet their needs and preferences, offer the device with the lowest cost.

NG3 Diabetes in pregnancy: management from preconception to the postnatal period https://www.nice.org.uk/guidance/ng3/

- **Offer** real-time continuous glucose monitoring (rtCGM) to all pregnant women with type 1 diabetes to help them meet their pregnancy blood glucose targets and improve neonatal outcomes.
- **Offer** intermittently scanned continuous glucose monitoring (isCGM, commonly referred to as 'flash') to pregnant women with type 1 diabetes who are unable to use rtCGM or express a clear preference for isCGM.

NG18 Children and Young Adults with diabetes https://www.nice.org.uk/guidance/ng18

- **Offer** real-time continuous glucose monitoring (rtCGM) to all children and young people with type 1 diabetes, alongside education to support children and young people and their families and carers to use it.
- Offer intermittently scanned continuous glucose monitoring (isCGM, commonly referred to as 'flash') to children and young people with type 1 diabetes aged 4 years and over who are unable to use rtCGM or who express a clear preference for isCGM.

NG28: Type 2 diabetes

- Offer intermittently scanned continuous glucose monitoring (isCGM, 'flash') to adults with type 2 diabetes on multiple daily insulin injections if any of the following apply:
    1. Recurrent hypoglycaemia or severe hypoglycaemia
    2. Impaired hypoglycaemia awareness
    3. Condition or disability (including a learning disability or cognitive impairment) that means they cannot self-monitor their blood glucose by capillary blood glucose monitoring but could use an isCGM device (or have it scanned for them)
    4. Would otherwise be advised to self-measure at least 8 times a day.
- Offer isCGM to adults with insulin-treated type 2 diabetes who would otherwise need help from a care worker or healthcare professional to monitor their blood glucose
- The advice of NICE when choosing a CGM device is to use shared decision making to identify the person's needs and preferences, and offer them an appropriate device, if multiple devices meet their needs and preferences, offer the device with the lowest cost

5. Suggestions for formulary

Looking at the devices that met our essential criteria and using the information provided by the manufacturers the following has been mapped against the NICE guidance for each cohort of patients, the following suggestions are made by clinicians who have already been providing CGM devices for those under an NHS pilot and a commercial study.

We ask that Nottingham and Nottinghamshire APC review these suggestions and the guidance for clinicians in both primary and secondary care settings to help them decide on the Nottingham and Nottinghamshire formulary.

For Type 1 patients

NG17: Type 1 Diabetes	Primary Care Prescribing via FP10	Secondary Care Prescribing via NHS Supply Chain	
		For patients on a pump	Options for patients with impaired awareness of hypoglycaemia or needing 3rd party share and follow functions and not on a pump
Offer adults with type 1 diabetes a choice of real-time continuous glucose monitoring (rtCGM) or intermittently scanned continuous glucose monitoring (isCGM, commonly referred to as 'flash'), based on their individual preferences, needs, characteristics, and the functionality of the devices available -16 factors to consider.	See APC formulary	CGM compatible with a pump*	Dexcom 7,Libre 3 or Guardian 4 Link

* Scenarios where rtCGM may be the best option are:
1. Those who are unable to scan their reader.
2. Those who want to/or need to place their sensort at an alternative site.
3. Those who have problems with adhesions with isCGM.
4. Those using smart pens where use of rtCGM allows data to be collated within a single system.

** Compatable choices for those on pumps
Dexcom G6 - suitable with Tandem, Omnipod, Ypsomed, Cam APS, Diabeloop
Guardian™ 3 Link - suitable with MiniMed™ 640G, MiniMed™ 670G
FreeStyle Libre 3® - suitable with Insulet, Tandem, Ypsomed
A8 TouchCare Nano - Suitable with Medtrum A8 TouchCare Nano Patch Pump
Guardian™ 4 Link - suitable with MiniMed™ 780G

For Pregnant Women

Choices will be consistent with the offer above for Type 1 patients.

For Children and Young People

NG18: Children and Young Adults with Diabetes	Secondary Care Prescribing via NHS Supply Chain
Offer real-time continuous glucose monitoring (rtCGM) to all children and young people with type 1 diabetes, alongside education to support children and young people and their families and carers to use it.	Age 2 upwards - Dexcom 1 Age 2 upwards - Dexcom 6 – suitable with Tandem, Omnipod, Ypsomed, Cam APS, Diabeloop Age 2 upwards – A8 TouchCare Nano – suitable with Medtrum A8 TouchCare Nano Patch Pump Age 4 upwards – Freestyle Libre – suitable with Insulet, Tandem, Ypsomed Age 7 upwards – Guardian 4 Link – suitable with MiniMed 780G All ages – Guardian 3 Link – suitable with MiniMed 640G, MiniMed 670G
Offer intermittently scanned continuous glucose monitoring (isCGM, commonly referred to as 'flash') to children and young people with type 1 diabetes aged 4 years and over who are unable to use rtCGM or who express a clear preference for isCGM.	Age 2 upwards – Freestyle Libre 2

For Type 2 patients

NG28: Type 2 Diabetes	Primary Care Prescribing via FP10	Secondary Care Prescribing via NHS Supply Chain
Offer intermittently scanned continuous glucose monitoring (isCGM, 'flash') to adults with type 2 diabetes on multiple daily insulin injections if any of the following apply:	.	
1.Recurrent hypoglycaemia or severe hypoglycaemia	See APC formulary. If ongoing problems refer to Secondary Care	Dexcom 7, Libre 3, Guardian 4, A8 TouchCare Nano
2.Impaired hypoglycaemia awareness	See APC formulary. If ongoing problems refer to Secondary Care	Dexcom 7, Libre 3, Guardian 4, A8 TouchCare Nano
3.Condition or disability (including a learning disability or cognitive impairment) that means they cannot self-monitor their blood glucose by capillary blood glucose monitoring but could use an isCGM device (or have it scanned for them)	See APC formulary. If ongoing problems refer to Secondary Care	Dexcom 7, Libre 3, Guardian 4, A8 TouchCare Nano
4.Would otherwise be advised to self-measure at least 8 times a day	See APC formulary. If ongoing problems refer to Secondary Care	Dexcom 1, Dexcom 7, Libre 3

6. Useful Device Information

A table showing some of the features of each device can be found on the following page and may be helpful for clinicians particularly for discussions with Type 1 patients around the 16 factors.

NG17 Type 1 diabetes	A8 TouchCare Nano CGM	FreeStyle Libre 3 Continuous CGM	Freestyle Libre 2 CGM	Guardian™ 3 Link Starter Kit	Guardian™ 4 Link Starter Kit	Dexcom One	Dexcom G6	Dexcom G7	GlucoMen Day CGM
	rtCGM	rtCGM	isCGM	rtCGM	rtCGM	rtCGM	rtCGM	rtCGM	rtCGM
	NHS SUPPLY CHAIN	NHS SUPPLY CHAIN	FP10	NHS SUPPLY CHAIN	NHS SUPPLY CHAIN	FP10	NHS SUPPLY CHAIN	NHS SUPPLY CHAIN	FP10 From Sept
Real time data sharing with alerts	Yes	Yes	No	Yes	Yes	No	Yes	Yes	Yes
Predictive alarms for high readings	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Predictive alarms for low readings	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Predictive alarms	Yes	No	No	Yes	Yes	No	Yes	Yes	Yes
Device situation on the body	Arms	Upper arm	Upper arm	Back of upper arm, Abdomen	7-17 y.o. - Upper buttocks, Back of the upper arm; 18 y.o. and older - Back of the upper arm, Abdomen	Placement sites are abdomen and back of arm (all ages) and additional placement site of top of buttocks (2-17 years)	Placement sites are abdomen and back of arm (all ages) and additional placement site of top of buttocks (2-17 years)	All patients can use their abdomen and back of upper arm. Patients 2 to 6 years old can also choose their upper buttocks	Abdomen or arm
Water resistence	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Size and weight	28.3 mm x 17.8 mm x 5.1 mm 2.15 g	2.9 mm (Height) x 21 mm (Diameter) and weighs 1g.	5mm (Height) x 35mm (Diameter) and weighs 5g.	3.8 x 6.7 x 5.2 centimeters (1.5 x 2.6 x 2.0 inches), 2.8 g; transmitter - 1.4" x 1.1" x 0.3", 5 g	3.8 x 6.7 x 5.2 centimeters (1.5 x 2.6 x 2.0 inches), 2.8 g; transmitter - 1.4" x 1.1" x 0.3", 5 g	size 1.8x 1.2 x 0.6 inches – weight 11.9 grams	Size - 1.8x 1.2 x 0.6 inches – weight 11.9 grams	Size - 2.74cm x 2.41cm x 0.47cm (L x W x H) Weight - 3.3g	3.5 x 2.5 x 0.7 cm
Frequency of sensor replacement	10-14 days	14 days	14 days	up to 168 hours	up to 168 hours	10 days	10 days	10 days + 12 hours grace period	14 days
Data sharing with HCP with patient consent	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Data Platforms for sharing with HCPs	Medtrum EasyView Pro website	LibreView . The LibreLinkUp app can be used by third parties, for example family members or caregivers, to access glucose data stored in LibreView, and alarms issued by the FreeStyle LibreLink app.	LibreView . The LibreLinkUp app can be used by third parties, for example family members or caregivers, to access glucose data stored in LibreView, and alarms issued by the FreeStyle LibreLink app.	CareLink™	CareLink™	Clarity, Diasend/ Glooko, Tidepool	Clarity, Diasend/ Glooko, Tidepool	Clarity, Diasend/ Glooko, Tidepool	Diasend and GlucoLog Web
Calibration requirements	Possible	Not Required	Not required	Required	Possible	Possible	Possible	Possible	Required
Compatability with Pumps	Compatable with Medtrum A8 TouchCare Nano Patch Pump	Compatable with Insulet, Tandem, Ypsomed	None as @July 2022	Compatable with MiniMed™ 640G, MiniMed™ 670G	Compatable with MiniMed™ 780G	None as @ July 2022	Compatable with Tandem, Omnipod, Ypsomed, Cam APS, Diabeloop	None as @ July 2022	None as @ July 2022
Compatability with Closed Loop	Yes	No	No	Yes	yes	No	Yes	No	Yes
Does this device require a smartphone	Yes	Yes	Yes	No	No	Yes	Yes	Yes	No
Does this device have IOS Compatability	Yes	Not currently	Yes	Yes	Yes	yes	yes	yes	yes
Does the device have Android compatability	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	No
Suitability for those with visual impairment	Yes	Yes	Yes	No	No	Yes	Yes	Yes	Yes
Suitability for those with hearing impairment	Yes	Yes	Yes	No	No	Yes	Yes	Yes	Yes
Easy read formats or alternative formats for those with learning diabilities	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Is a reader available from the manufacturer? (if required)	Yes	No	Yes	Not applicable - not required	Not applicable - not required	Yes	Yes	Yes	Yes

7. Device costs

The above recommendations have been made based on the NICE cost effectiveness analysis finding that the technologies are a cost-effective intervention in the above circumstances. Overall NICE have deemed both Intermittently scanned (flash or isCGM) and real time rtCGM cost effective interventions with an Incremental Cost-Effectiveness Ratio (ICER) of £10,157 for isCGM vs SMBG and ICER of £16,351 for rtCGM vs SMBG. The studies on which these analyses were based can be found at: https://www.nice.org.uk/guidance/ng17/evidence/b-continuous-glucose-monitoring-in-adults-with-type-1-diabetes-pdf-11013435182.

This data was published before the Flash UK randomised controlled trial, which is the most robust data to date evaluating the cost effectiveness of the Freestyle libre® 2 device. In this trial the **ICER was £5,191**, deemed by a NICE health economic analyst as **"highly cost effective"**. An ICER under £20,000 is deemed cost effective by NICE

The ABCD audit demonstrates that use of the FreeStyle Libre® (flash or isCGM) system reduces diabetes-related resource utilisation. The cost analysis found that higher acquisition costs are offset by healthcare costs avoided. **The difference was found to be £168 per patient per year** (PPPY). Total costs were £1116 PPPY with FreeStyle Libre® system compared with £948 PPPY with Self-monitoring of blood glucose (SMBG).

CGM reduces the risk of acute events such as admissions due to diabetic ketoacidosis, hypoglycaemia and improves HbA1c which will reduce the risk of longer-term complications. As such, the terminology in the NICE guidance is to offer the technology, not to consider.

There are two categories of continuous glucose monitoring products, those available on FP10 and those which are available through NHS Supply chain and are considered 'high cost'. A summary of the costs of each option that met our essential criteria can be found on the next page.

FP10 products actual cost

Category	Product	Annual cost	Sensors details	
isCGM	FreeStyle Libre 2®	£910 – based on 26 sensors per year	Sensor life 14 days. £35 each	Reader FOC Transmitter: not required
rtCGM	Dexcom One®	£900 – based on 36 sensors per year	Sensor life 10 days. £25 each	Reader: FOC Transmitter: FOC

High Cost – NHS Supply chain products

Category	Product	Costs calculated per year					
		Device	Transmitter	Transmitter shelf life	Reader	Sensors	Sensor details & expected volume per year
rtCGM	A8 TouchCare Nano	£200	£200	1 year	£0***	£1,260	Sensor life 10-14 days. Sensors sold in packs of 2 at £70. Calculated on 18 packs per year
rtCGM	FreeStyle Libre 3	£FOC	N/A	N/A	Not availabl e	£1,118	Sensor life 14 days. 26 sensors per year @ £43 each
rtCGM	Guardian™ 3 Link Starter Kit	£490*	£350	6mths	£0	£2,375	Sensor life 168 hrs)7 days) Sensors sold in packs of 15 @ £708.75

rtCGM	Guardian™ 4 Link Starter Kit	£490*	£350	6mths	£0	£2,375	Sensor life 168 hrs (7 days) Sensors sold in packs of 15 @ £708.75
rtCGM	Dexcom G6	£FOC	£200	12 mth	£290**	£1,845	Sensor life 10 days. 36 sensors per year @ £51.25 each
rtCGM	Dexcom G7	£FOC	N/A	N/A	£250**	£1,845	Sensor life 10 days + 12hour grace period. 36 sensors per year @ £51.25 each

*includes Transmitter, Charger, Tester / Cleaning plugs, battery, One Press Serter

**Optional if required by patient

*** If using standalone Medtrum EasySense app on users smartphone is reader (free) If used with pump PDM reader included with pump cost

8. Future actions

Request for devices outside the agreed formulary

We expect that this options appraisal will result in a wide range of options and choices being available to cater for patient's needs and allow us to implement NICE guidance. However, we recognise that in some cases it may be necessary for secondary care colleagues to request devices that are not in the agreed formulary. This route should only be used for patients meeting the agreed cohorts for CGM who have a clinical need for a non-formulary device due to exceptional circumstances. It should not be used as a route for patient preference only.

Ongoing evaluation of new products and review of agreed formulary

If the ICB becomes aware of new products coming onto the market, we will contact the manufacturer and request that they complete the same 54 questions we have employed for this process. The responses will be assessed against the same criteria we have agreed for this initial options appraisal and will be brought to Nottingham and Nottinghamshire APC for consideration for adding to our formulary at that time.

If we become aware of any issues with any of the CGM devices, we will review their suitability for the formulary at that time via Nottingham and Nottinghamshire APC.

9. Appendix

9.1 Relevant Studies (small selection)

- **Reductions in HbA1c, hypoglycaemia admissions, DKA admissions and the occurrence of major complications for those living with Diabetes.**
    - Relief Study - https://diabetesjournals.org/care/article/44/6/1368/138708/Important-Drop-in-Rate-of-Acute-Diabetes
    - Bergenstal et al: acute events in T2DM https://pubmed.ncbi.nlm.nih.gov/33644623/
    - Baxter et al (https://onlinelibrary.wiley.com/doi/epdf/10.1111/dme.13062)

- **Psychological benefits, Reduction in frequency of clinician follow up**

    - Flash UK Study

- **Budget Impact and cost effectiveness**
    - ABCD FreeStyle® Libre Nationwide Audit https://drc.bmj.com/content/bmjdrc/10/2/e002580.full.pdf
    - Flash UK Study

9.2 Useful information and terminology

Making decisions using NICE guidelines
www.nice.org.uk/about/what-we-do/our-programmes/nice-guidance/nice-guidelines/making-decisions-using-nice-guidelines
Some recommendations are made with more certainty than others

- Where there is clear and strong evidence of benefit, we use the word **'offer'**
- Where the benefit is less certain we use the word **'consider'**

Terminology in relation to CGM

- **Continuous glucose monitoring (CGM)** – systems that track glucose levels through a sensor inserted under the skin of the abdomen or arm. CGM can be used with or without an insulin pump. There are 2 types:

    - Real time CGM (rtCGM) – sensor tracks glucose levels throughout the day & night; some can alert if levels go too high/low. Results sent to receiver or smart device. (Examples include Dexacom G6, GluoMen Day, Guardian Connect, GlucoRx Aidex)

- Intermittently scanned CGM (isCGM or flash CGM) – sensor does not automatically send readings, users swipe the receiver or smartphone over it to get readings. (Examples include FreeStyle Libre)

- **Self-monitoring of blood glucose (SMBG) – intermittent finger prick testing using test strips**

9.3 Copy of the questionnaire sent to manufacturers

Flash and CGM device questionnaire f

9.4 Full device information provided by manufacturers collated into usable table.

Diabetes Tech - Device info table.xlsx