Medicines Management Programme

Preferred continuous glucose monitoring sensor(s) with associated system(s)

Evaluation report

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List of Abbreviations

App	Application
BGTS	Blood glucose test strips
CDS	Community Drug Schemes
CGM	Continuous glucose monitoring
CSII	Continuous subcutaneous insulin infusion
DP	Drugs Payment (scheme)
GMS	General Medical Services (scheme)
HCL	Hybrid closed loop
HCP	Healthcare professional
HIQA	Health Information and Quality Authority
HSE	Health Service Executive
HTA	Health technology assessment
isCGM	Intermittently scanned continuous glucose monitoring
LTI	Long Term Illness (scheme)
MARD	Mean absolute relative difference
MMP	Medicines Management Programme
PCRS	Primary Care Reimbursement Service
SMBG	Self-monitoring of blood glucose
rtCGM	Real-time continuous glucose monitoring
T1DM	Type 1 diabetes mellitus
VAT	Value-added tax

Definitions

For the purposes of this document, the reimbursement price refers to the price as listed on the reimbursement list, available on the Health Service Executive-Primary Care Reimbursement Service website, www.pcrs.ie. Reimbursement prices are correct as of 01/07/2024, unless otherwise stated.

Acquisition cost, when referred to in this document, refers to the acquisition cost to the Primary Care Reimbursement Service, based on the published reimbursement price, and excludes value-added tax and pharmacy fees.

For the purpose of this document, diabetes mellitus may also be referred to as diabetes.

The term supplier refers to a company that has submitted a continuous glucose monitoring sensor(s) with associated system(s) for inclusion in this evaluation process, and may include a manufacturer, distributor or agent for the continuous glucose monitoring sensor(s) with associated system(s).

1. Executive summary

The Health Service Executive (HSE)-Medicines Management Programme (MMP) aims to support safe, effective and cost-effective prescribing in the Irish healthcare setting.

In 2023, continuous glucose monitoring (CGM) sensors accounted for a total expenditure of approximately €55.72 million under the Community Drug Schemes (CDS).

The aim of this initiative is to identify preferred CGM sensor(s) with associated system(s). The use of preferred CGM sensor(s) with associated system(s) will realise efficiencies in this area.

The identification of the preferred CGM sensor(s) with associated system(s) was carried out in accordance with the evaluation process outlined in the *HSE-MMP roadmap for the identification of preferred continuous glucose monitoring sensor(s) with associated system(s).*

The MMP has identified two preferred CGM sensors (List A) with associated systems, for people with diabetes requiring CGM[i] who are not insulin pump users.

Preferred CGM sensors – List A		
CGM sensor	**Reimbursement code**	**Pack size**
Freestyle Libre 2	85581	1
Dexcom ONE+	97636	1

The MMP recommends a preferred CGM sensor with associated system from List A for people with diabetes[i] requiring CGM who are not insulin pump users, when:

- First initiating CGM
- Continuing CGM upon review
- Changing CGM sensor with associated system

Implementation of the preferred CGM sensors will lead to significant savings for the HSE, in the order of millions of euros.

[i]Reimbursement is supported in accordance with Primary Care Reimbursement Service circular 033/23 Continuous Glucose Monitoring (CGM) Reimbursement Application System.

2. Purpose

The purpose of this evaluation is to identify preferred CGM sensor(s) with associated system(s), as part of the MMP's remit to support safe, effective and cost-effective prescribing in the Irish healthcare setting.

3. Scope

This evaluation considers CGM sensors on the HSE-Primary Care Reimbursement Service (PCRS) reimbursement list with their associated system(s), which are currently available for supply to the Irish Market. Evaluation under the criteria outlined below is limited to CGM sensor(s) with associated system(s) that were submitted for inclusion during the evaluation as part of the *HSE-MMP roadmap for the identification of preferred continuous glucose monitoring sensor(s) with associated system(s),* and where the submission included an accompanying cover page (see section 9.1) for the CGM sensor(s) with associated system(s).

This evaluation is aimed at achieving efficiencies by the identification of preferred CGM sensor(s) with associated system(s).

CGM sensors are reimbursed under the CDS. Associated equipment (e.g. transmitters and readers/receivers), where required, are managed through HSE Community Funded Schemes, administered by the Local Health Office of the area in which the person resides. Information regarding the reimbursement price of CGM sensors, excluding the cost of associated equipment, is provided in this document.

4. Background

Diabetes mellitus is defined by the World Health Organisation as a chronic, metabolic disease, characterised by elevated levels of blood glucose, which leads over time to serious damage to the heart, blood vessels, eyes, kidneys and nerves. There are different types of diabetes, including type 1 diabetes mellitus (T1DM), type 2 diabetes mellitus and gestational diabetes.[1, 2]

CGM systems provide an alternative approach to using blood glucose test strips (BGTS) for self-monitoring of blood glucose (SMBG), by measuring glucose levels in the interstitial fluid (a thin layer of fluid around the cells). These systems comprise sensors (self-administered subcutaneously, and replaced every 7 to 14 days depending on the system), transmitters (or combined sensors and transmitters), and a mechanism to display the results (readers/receivers or smart device application

[app]). There are two types of CGM systems; real-time CGM (rtCGM) and intermittently scanned CGM (isCGM).[3]

CGM sensors can be accessed under the CDS, as they are included on the PCRS reimbursement list.[4] For CGM sensors to be included on the reimbursement list, they must have satisfied the certification process, in accordance with the relevant PCRS guidelines in place at the time of their addition to the reimbursement list. The current guidelines for this process are entitled *HSE-PCRS Diabetes Consumables Guidelines for Suppliers/Manufacturers/Distributors (November 2023)*.[5] This process is underpinned by the Health (Pricing and Supply of Medical Goods) Act 2013.[6]

The Health Products Regulatory Authority has a regulatory role involving the monitoring of medical devices (e.g. CGM sensors) in Ireland including operating a national safety reporting system for medical devices.[7]

5. Health Information and Quality Authority Rapid Health Technology Assessment of Continuous Glucose Monitoring in Adults with Type 1 Diabetes Mellitus

Following a request from the office of the Chief Clinical Officer in the HSE, the Health Information and Quality Authority (HIQA) completed a rapid health technology assessment (HTA) of CGM in adults with T1DM.[3] The rapid HTA, published in September 2023, provided advice on the clinical-effectiveness, cost-effectiveness, and budget impact of providing CGM for adults with T1DM. This assessment includes a number of recommendations and advice points, the following of which are relevant to this evaluation:

- Switching to an economically advantageous CGM system, when clinically appropriate to do so, may result in cost savings for the HSE.
- Given the higher cost of the rtCGM systems and limited evidence to demonstrate their benefit over and above isCGM devices, a consideration would be whether those currently on rtCGM systems be switched to isCGM.[3]

6. National Clinical Guideline: Adult Type 1 Diabetes Mellitus

The Department of Health updated the national clinical guideline for adults with T1DM in May 2024, entitled *Adult Type 1 Diabetes Mellitus v2, National Clinical Guideline No.17 May 2024*.[8] Part of the process of developing this guideline involved contextualising the National Institute for Health and

Care Excellence guideline NG17, "Type 1 diabetes in adults: diagnosis and management," for use in Ireland.[9]

The updated guideline includes information in relation to the use of CGM systems in adults with T1DM.

7. Diabetes mellitus & CGM – expenditure and utilisation

The Long Term Illness (LTI) scheme is a non-means tested, condition specific, prescription charge exempt primary care scheme operationalised by the PCRS. The scheme commenced in 1970 through the Health Act (1970) and was last amended in 1975. The scheme provides medicines and consumable appliances for the treatment of diabetes mellitus free of charge.[10] In 2022, total expenditure by the PCRS for diabetes mellitus on the LTI scheme was €253.96 million.[11] This expenditure reflected utilisation by 157,777 people in Ireland. The majority of expenditure for diabetes management is under this scheme with some additional expenditure under the General Medical Services (GMS) and Drugs Payment (DP) schemes.

According to MMP analysis[ii], there has been an increase in utilisation and total expenditure on CGM sensors, under the CDS (DP, GMS, LTI schemes) over the last three years. The number of individuals in receipt of CGM sensors under the CDS on a monthly basis between January 2021 and December 2023, increased from approximately 6,000 to 16,900, while total monthly expenditure increased from approximately €1.57 million to €5.35 million. Total expenditure on CGM sensors under the CDS in 2023 was estimated by the MMP to be approximately €55.72 million.[12]

In light of this significant increase in expenditure and recommendations from the HIQA rapid HTA, the HSE introduced a reimbursement application system for all CGM sensors on the reimbursement list in December 2023 in accordance with PCRS Circular 033/23.[13]

8. Identification of the preferred CGM sensor(s)

The identification of the preferred CGM sensor(s) with associated system(s) was carried out in accordance with the evaluation process outlined in the *HSE-MMP roadmap for the identification of preferred continuous glucose monitoring sensor(s) with associated system(s).*

[ii]Utilisation and total expenditure are based on data from all age groups. Total expenditure includes ingredient cost, pharmacy fees and value-added tax (VAT), where applicable, based on claims submitted by pharmacists.

8.1 MMP roadmap

The MMP published the *HSE-MMP roadmap for the identification of preferred continuous glucose monitoring sensor(s) with associated system(s)* on 9 November 2023. A copy of the roadmap is available in Appendix A.

8.2 MMP evaluation process

As part of the evaluation process for the identification of preferred CGM sensor(s) with associated system(s), a period of consultation with stakeholders was undertaken between 9 November 2023 and 7 December 2023. Suppliers of CGM sensors on the reimbursement list were notified of publication of the roadmap and of the commencement of the evaluation process. Information in relation to the evaluation process was published on the MMP's website and a notice was issued from the MMP's X (Twitter) account. The National Clinical Programme for Diabetes was also notified of the publication of the roadmap and of the commencement of the evaluation process.

9. Evaluation

9.1 Cover page

For a CGM sensor to be considered for inclusion in this process, suppliers were required to complete and sign a cover page, confirming compliance of the submitted CGM sensor and associated systems with:

- Applicable national standards and European Commission standards
- All applicable laws.

A copy of the cover page is available in Appendix B.

9.2 Criteria

In line with the *HSE-MMP roadmap for the identification of preferred continuous glucose monitoring sensor(s) with associated system(s)*, the MMP considered the following criteria when identifying the preferred list:

1. Acquisition cost of the CGM sensor
2. CGM sensor features
3. Associated system features (and acquisition costs if applicable)
4. Expenditure in the area and potential for cost efficiencies
5. Provision of patient support services by the supplier
6. Provision of education resources to healthcare professionals (HCP) by the supplier
7. Robustness of supply of CGM sensor with associated system to the Irish Market

8. Patient factors
9. Any other relevant factors (e.g. requirement for calibration with BGTS).

In relation to the submissions received from suppliers during the evaluation process, the nine criteria above were employed in identifying the preferred CGM sensor(s). The MMP evaluated eight individual CGM sensors with associated systems from four suppliers under these criteria. The MMP reviewed information as submitted by suppliers and in cases where further information was required, this was requested as part of the evaluation process.

Table 1 outlines the CGM sensor submissions received from suppliers during the evaluation process.

Table 1: CGM sensor submissions received from suppliers during the evaluation process

Supplier	Reimbursement code	CGM sensor*
Abbott Diabetes Care	85581	Freestyle Libre 2
Dexcom	97628, 97629	Dexcom G6
Dexcom	97631	Dexcom G7
Dexcom	97636	Dexcom ONE+
Medtronic	97645	Medtronic Guardian™ Sensor 4 MMT-7040C1
Medtronic	97671	Medtronic Guardian™ Sensor 4 MMT-7040QC1
Medtronic	97680	Medtronic Guardian™ Sensor 3 MMT-7020C1
Windzor Pharma Ltd	85241	GlucoRx Aidex™

*Listed alphabetically by supplier name.

Submissions were also received from HCP and patient organisations, which were given due consideration throughout this evaluation. Table 2 outlines the submissions received.

Table 2: Submissions received from healthcare professional and patient organisations

Stakeholder
National Clinical Programme for Diabetes
National Clinical Programme for Paediatrics & Neonatology
Diabetes Service, St. Columcille's Hospital, Loughlinstown
A consultant endocrinologist
Diabetes Ireland

9.2.1 Acquisition cost of the CGM sensor

The acquisition cost of the CGM sensors that were submitted as part of the *MMP evaluation for the identification of preferred continuous glucose monitoring sensor(s) with associated system(s)* were considered under this criterion.

As part of the evaluation eight individual CGM sensors on the PCRS reimbursement list, with nine presentations based on pack size, were submitted.[4]

Information outlined in table 3 includes the reimbursement price, cost per day and annual cost to the HSE per person, for each CGM sensor submitted as part of this evaluation.

Table 3: Reimbursement price, cost per day and annual cost to the HSE per person, for each CGM sensor under the Community Drug Schemes as of July 2024

Product	Reimbursement code	Pack Size	Reimbursement price* (€)	Sensor duration	Cost per day **β (€)	Annual cost to the HSE**ϒ (€)
Freestyle Libre 2	85581	1	44.00	14 days	3.14	1,499.88
Dexcom G6	97628	1	68.00	10 days	6.80	3,137.02
Dexcom G6	97629	3	204.00	10 days	6.80	3,137.02
Dexcom G7	97631	1	68.00	10 days (12 hour grace period)	6.80	3,137.02
Dexcom ONE+	97636	1	31.62	10 days (12 hour grace period)	3.16	1,502.62
Medtronic Guardian™ Sensor 4 MMT-7040C1	97645	5	247.50	Up to 7 days	7.07	3,247.23
Medtronic Guardian™ Sensor 4 MMT-7040QC1	97671	5	247.50	Up to 7 days	7.07	3,247.23
Medtronic Guardian™ Sensor 3 MMT-7020C1	97680	5	247.50	Up to 7 days	7.07	3,247.23
GlucoRx Aidex™	85241	1	35.34	14 days	2.52	1,221.98

*Reimbursement price correct as of 01/07/2024; **Does not account for higher quantities, which may be required due to the available pack size. Assumes each sensor is worn for the maximum wear time; βBased on the reimbursement price, exclusive of pharmacy fees and value-added tax (VAT); ϒInclusive of pharmacy fees and VAT

As outlined in table 3, the cost per day for the individual CGM sensors ranges from €2.52 to €7.07. In 2023, CGM sensors with a higher cost per day (i.e. greater than or equal to €6.80) accounted for the majority of expenditure in that year under the CDS.[12]

Submissions received during the evaluation process included revised reimbursement prices for some of the CGM sensors listed in table 3, resulting in a reduction in the cost per day and annual cost to the HSE per person for certain CGM sensors, when compared with 2023.

Recommendation

In relation to the criterion of acquisition cost of CGM sensors, the MMP is of the opinion that CGM sensors with a lower cost per day should be considered for inclusion in the preferred list of CGM sensors, once all other criteria have also been satisfied.

Currently, a cost per day of less than or equal to €3.16 captures more than one option for patients and prescribers to choose from, while also allowing for efficiencies to be generated.

9.2.2 CGM sensor features

The features of the CGM sensors that were submitted as part of *the MMP evaluation for the identification of preferred continuous glucose monitoring sensor(s) with associated system(s)* were considered under this criterion. Several aspects of CGM sensor features were considered, based on the information outlined in submissions, including:

- CGM sensor type
- Warm up time of CGM sensor
- Adjunctive status and calibration details
- Age requirement for the CGM sensor
- Application site of CGM sensor
- Accuracy of the CGM sensor
- Lifespan of CGM sensor
- Size of CGM sensor
- Details of water-resistant or waterproof nature of CGM sensor.

9.2.2.1 CGM sensor type

The CGM sensors considered as part of this evaluation were classified by suppliers as either isCGM sensors and/or rtCGM sensors. The classification of sensor type of each CGM sensor submitted is outlined in table 4.

Table 4: Sensor type of each CGM sensor submitted

CGM sensor	Sensor type
Freestyle Libre 2	rtCGM when Freestyle LibreLink App on a smartphone is used, isCGM when the reader is used as the display device
Dexcom G6	rtCGM
Dexcom G7	rtCGM
Dexcom ONE+	rtCGM
Medtronic Guardian™ Sensor 4 MMT-7040C1	rtCGM
Medtronic Guardian™ Sensor 4 MMT-7040QC1	rtCGM
Medtronic Guardian™ Sensor 3 MMT-7020C1	rtCGM
GlucoRx Aidex™	rtCGM

App: application; isCGM: intermittently scanned continuous glucose monitoring; rtCGM: real-time continuous glucose monitoring

All CGM sensors submitted have rtCGM capability. All CGM sensors, except the FreeStyle Libre 2 CGM sensor, provide rtCGM through all of the available display devices. When Freestyle Libre 2 CGM sensor is used with the Freestyle LibreLink smartphone app, real-time glucose readings are transmitted every minute to the user's smartphone, i.e. rtCGM classification. If using a Freestyle Libre 2 reader as the display device, the sensor updates readings every minute, however the user must scan the CGM sensor for glucose readings to be displayed i.e. isCGM classification.

9.2.2.2 Warm up time of CGM sensor

The initial warm up time for each CGM sensor submitted is outlined in table 5.

Table 5: Warm up time for each CGM sensor submitted

CGM sensor	Warm up time
Freestyle Libre 2	60 minutes
Dexcom G6	120 minutes
Dexcom G7	30 minutes
Dexcom ONE+	30 minutes
Medtronic Guardian™ Sensor 4 MMT-7040C1	120 minutes
Medtronic Guardian™ Sensor 4 MMT-7040QC1	120 minutes
Medtronic Guardian™ Sensor 3 MMT-7020C1	120 minutes
GlucoRx Aidex™	60 minutes

9.2.2.3 Adjunctive status and calibration details

CGM systems may be adjunctive, that is, they should be used in conjunction with SMBG using a BGTS and associated meter before making a treatment decision, or non-adjunctive, that is, no SMBG with BGTS is required.[3]

An overview of the current adjunctive status and calibration details, for each CGM sensor submitted, is outlined in table 6.

Table 6: Adjunctive status and calibration details for each CGM sensor submitted

CGM sensor	Adjunctive status	Factory calibrated	Capillary glucose calibration required	Capillary glucose calibration optional
Freestyle Libre 2	No	Yes	No	No*
Dexcom G6	No	Yes	No	Yes
Dexcom G7	No	Yes	No	Yes
Dexcom ONE+	No	Yes	No	Yes
Medtronic Guardian™ Sensor 4 MMT-7040C1	No	Yes	No	Yes
Medtronic Guardian™ Sensor 4 MMT-7040QC1	No	Yes	No	Yes
Medtronic Guardian™ Sensor 3 MMT-7020C1	Yes	No	Yes	No**
GlucoRx Aidex™	Yes	Yes	No	Yes

*Not required for CGM sensor to function; **Calibration is required for this CGM sensor to function as intended. Additional calibrations over the minimum calibration requirements can be performed.

Further information

Medtronic Guardian™ Sensor 3 MMT-7020C1 and GlucoRx Aidex™ sensors are both classified as adjunctive. The user guide for GlucoRx Aidex™ states that "measurements should not be used to make treatment adjustments, but rather as a reminder of when fingertip testing is required". The instructions for use of the MiniMed™ 740G system, which utilises the Medtronic Guardian™ Sensor 3 MMT-7020C1, states that "The MiniMed™ 740G System CGM does not replace a blood glucose meter". Medtronic advises that the user should always use the values from their blood glucose meter for treatment decisions.

The remaining CGM sensors are non-adjunctive and so their glucose readings can be used to make treatment decisions without SMBG using a BGTS with associated meter.[3] However, SMBG using BGTS is still required with non-adjunctive CGM systems in certain scenarios. For example, people with diabetes are typically still cautioned to use SMBG to make treatment decisions if alerts and readings from their CGM system do not match their symptoms or expectations.

9.2.2.4 Age requirement for the CGM sensor

The age requirement for each CGM sensor submitted is outlined in table 7.

Table 7: Age requirement for each CGM sensor submitted

CGM sensor	Age requirement for system
Freestyle Libre 2	4 years and older. The indication for children (aged 4 to 12 years) is limited to those who are supervised by a caregiver who is at least 18 years of age.
Dexcom G6	2 years and older
Dexcom G7	2 years and older
Dexcom ONE+	2 years and older
Medtronic Guardian™ Sensor 4 MMT-7040C1	7 years and older
Medtronic Guardian™ Sensor 4 MMT-7040QC1	7 years and older
Medtronic Guardian™ Sensor 3 MMT-7020C1	No age restriction
GlucoRx Aidex™	14 years and older

9.2.2.5 Application site of CGM sensor

The application site for each CGM sensor submitted as part of the evaluation is outlined in table 8.

Table 8: Application site for each CGM sensor submitted

CGM sensor	Application site
Freestyle Libre 2	**Ages 4 years and older:** back of the upper arm
Dexcom G6	**Ages 2 to 17 years**: abdomen, upper buttocks, back of upper arm **Adults:** abdomen, back of upper arm
Dexcom G7	**Ages 2 to 6 years:** abdomen, upper buttocks, back of upper arm **Ages 7 years and older:** abdomen, back of upper arm
Dexcom ONE+	**Ages 2 to 6 years**: abdomen, upper buttocks, back of upper arm **Ages 7 years and older:** abdomen, back of upper arm
Medtronic Guardian™ Sensor 4 MMT-7040C1	**Ages 7 to 17 years:** upper buttocks, back of arm **Ages 18 years and older:** abdomen, back of upper arm
Medtronic Guardian™ Sensor 4 MMT-7040QC1	**Ages 7 to 17 years:** upper buttocks, back of upper arm **Ages 18 years and older:** abdomen, back of upper arm
Medtronic Guardian™ Sensor 3 MMT-7020C1	**All ages:** abdomen, arm
GlucoRx Aidex™	**Ages 14 years and older:** abdomen, back of upper arm

9.2.2.6 Accuracy of CGM sensor

The mean absolute relative difference (MARD) is the parameter most often used for description of the analytical performance of CGM systems. The MARD is computed using temporally matched glucose data from CGM systems and comparison glucose measurements (most often obtained by capillary blood glucose measurements) of all subjects of a clinical study. Reported as a percentage, MARD is the average of the absolute difference between these values. The lower the MARD is, the closer the CGM readings are to the comparison values.[14]

An overview of the accuracy, in terms of MARD, for each CGM sensor submitted, is outlined in table 9.

Table 9: Accuracy of each CGM sensor submitted

CGM sensor	Mean absolute relative difference
Freestyle Libre 2	**Ages 6 to 17 years:** 9.7% **Adults:** 9.2%
Dexcom G6	**Overall:** 9.0% **Ages 6 to 17 years:** 7.7% **Adults:** 9.8%
Dexcom G7	**Overall:** 8.2% **Ages 2 to 6 years:** 9.3% **Ages 7 to 17 years:** 8.1% for arm-placed sensors, 9.0% for abdomen-placed sensors **Adults:** 8.2% for arm-placed sensors, 9.1% for abdomen-placed sensors
Dexcom ONE+	**Overall:** 8.2% **Ages 2 to 6 years:** 9.3% **Ages 7 to 17 years:** 8.1% for arm-placed sensors, 9.0% for abdomen-placed sensors **Adults:** 8.2% for arm-placed sensors, 9.1% for abdomen-placed sensors
Medtronic Guardian™ Sensor 4 MMT-7040C1	**Overall:** 10.6%
Medtronic Guardian™ Sensor 4 MMT-7040QC1	**Overall:** 10.4% **Ages 7 to 17 years:** 11.6% for arm-placed sensors, 12.3% for abdomen-placed sensors **Adults**: 10.6% for arm-placed sensors, 10.8% for abdomen-placed sensors
Medtronic Guardian™ Sensor 3 MMT-7020C1	**Overall:** 10.5% **Ages 14 to 75 years, calibrating every 12 hours:** 9.1% for arm-placed sensors, 10.5% for abdomen-placed sensors **Ages 14 to 75 years calibrating 3 to 4 times daily**: 8.7% for arm-placed sensors, 9.5% for abdomen-placed sensors
GlucoRx Aidex™	**Overall:** 9.08%

9.2.2.7 Lifespan of CGM sensor

The lifespan for each CGM sensor submitted as part of the evaluation is outlined in table 10.

Table 10: Lifespan for each CGM sensor submitted

CGM sensor	Lifespan of CGM sensor
Freestyle Libre 2	14 days
Dexcom G6	10 days
Dexcom G7	10 days (12 hour grace period)
Dexcom ONE+	10 days (12 hour grace period)
Medtronic Guardian™ Sensor 4 MMT-7040C1	Up to 7 days
Medtronic Guardian™ Sensor 4 MMT-7040QC1	Up to 7 days
Medtronic Guardian™ Sensor 3 MMT-7020C1	Up to 7 days
GlucoRx Aidex™	14 days

9.2.2.8 Size of CGM sensor

An overview of the insertion depth of the CGM sensor filament and dimensions of the CGM sensor (plus the transmitter where applicable), for each CGM sensor submitted, is outlined in table 11.

Table 11: Insertion depth of filament and dimensions of each CGM sensor submitted

CGM sensor	Insertion depth of CGM sensor filament	Dimensions of CGM sensor (plus transmitter where applicable)
Freestyle Libre 2	5 mm	35 mm (D) × 5 mm (H) disk
Dexcom G6	11.4 mm below the skin at a 45-degree angle, which is 8 mm vertically	45.7 mm (L) x 30. 5mm (W) x 15.2 mm (H)
Dexcom G7	5.7 mm	27.4 mm (L) x 24.1 mm (W) x 4.7 mm (H)
Dexcom ONE+	5.7 mm	27.4 mm (L) x 24.1 mm (W) x 4.7 mm (H)
Medtronic Guardian™ Sensor 4 MMT-7040C1	9.3 mm	Approximate dimensions of sensor after it slots into the transmitter are 46 mm x 28 mm x 9.7 mm. “The sensor is a mushroom shape so these dimensions relate to the biggest dimensions if squared off”.
Medtronic Guardian™ Sensor 4 MMT-7040QC1	9.3 mm	Approximate dimensions of sensor after it slots into the transmitter are 46 mm x 28 mm x 9.7 mm. “The sensor is a mushroom shape so these dimensions relate to the biggest dimensions if squared off”.
Medtronic Guardian™ Sensor 3 MMT-7020C1	9.3 mm	Approximate dimensions of sensor after it slots into the transmitter are 46 mm x 28 mm x 9.7 mm. “The sensor is a mushroom shape so these dimensions relate to the biggest dimensions if squared off”.
GlucoRx Aidex™	8.8-9.8 mm	35 mm (L) x 21 mm (W) x 9 mm (H)

D: diameter; H: height; L: length; mm: millimetre; W: width

9.2.2.9 Details of water-resistant or waterproof nature of CGM sensor

Details of water-resistant or waterproof nature for each CGM sensor submitted are outlined in table 12.

Table 12: Details of water-resistant or waterproof nature for each CGM sensor submitted

CGM sensor	Details
Freestyle Libre 2	Water-resistant to a depth of 1 metre (up to 30 minutes). Swim, shower or take a bath without removing.
Dexcom G6	Water-resistant to a depth of 2.4 metres (up to 24 hours). Swim, shower or take a bath without removing.
Dexcom G7	Waterproof to a depth of 2.4 metres (up to 24 hours). Swim, shower or take a bath without removing.
Dexcom ONE+	Waterproof to a depth of 2.4 metres (up to 24 hours). Swim, shower or take a bath without removing.
Medtronic Guardian™ Sensor 4 MMT-7040C1	After the transmitter and sensor are connected, they form a waterproof seal to a depth of 2.4 metres (up to 30 minutes). Swim, shower or take a bath without removing.
Medtronic Guardian™ Sensor 4 MMT-7040QC1	After the transmitter and sensor are connected, they form a waterproof seal to a depth of 2.4 metres (up to 30 minutes). Swim, shower or take a bath without removing.
Medtronic Guardian™ Sensor 3 MMT-7020C1	After the transmitter and sensor are connected, they form a waterproof seal to a depth of 2.4 metres (up to 30 minutes). Swim, shower or take a bath without removing.
GlucoRx Aidex™	Waterproof and can withstand incidental exposure to water to a depth of 1 metre (for up to 30 minutes). Swim, shower or take a bath without removing.

Recommendation

In relation to the criterion of CGM sensor features, several aspects were considered. Overall, the MMP is of the opinion that a CGM sensor suitable for use by a wide range of age groups is preferable. In addition, a non-adjunctive CGM sensor is preferable to minimise the associated cost of additional SMBG using BGTS and lancets, and also to reduce the need for additional management by the patient. It is preferable to have an option of more than one preferred CGM sensor for patients and prescribers to choose from.

9.2.3 Associated system features

The features (and accompanying costs if applicable) of the associated systems for the CGM sensors that were submitted as part of the *MMP evaluation for the identification of preferred continuous glucose monitoring sensor(s) with associated system(s)* were considered under this criterion. Several different associated system features were considered based on the information outlined in submissions, including:

- Requirement for a separate transmitter
- Display devices
- Alerts and alarms
- System notifications when the CGM sensor (and transmitter if applicable) are approaching expiration

- Compatibility with other systems
- Data sharing features.

9.2.3.1 Transmitters

All of the CGM sensors submitted for review transmit information from the CGM sensor to their display device via Bluetooth. The frequency of transmission of signal to the display device varies on the individual CGM sensor:

- Freestyle Libre 2: Every minute when using Freestyle LibreLink App on a smartphone
- Dexcom G6, Dexcom G7 and Dexcom ONE+: Every 5 minutes
- Medtronic Guardian™ Sensor 4 MMT-7040C1, Medtronic Guardian™ Sensor 4 MMT-7040QC1 and Medtronic Guardian™ Sensor 3 MMT-7020C1: Continuous with readings displayed every 5 minutes
- GlucoRx Aidex™: Every 5 minutes.

Some CGM sensors require a transmitter which is separate from the CGM sensor to function. For others, the transmitter is embedded or built-in to the CGM sensor. Details of the requirement for a separate transmitter and the associated costs are outlined in table 13.

Table 13: Transmitter information of each CGM sensor submitted

CGM sensor	Separate transmitter required	Funding route	Cost associated with transmitter	Life of transmitter
Freestyle Libre 2	No	n/a	n/a	n/a
Dexcom G6	Yes	Accessed through Local Health Office	No	90 day battery life
Dexcom G7	No	n/a	n/a	n/a
Dexcom ONE+	No	n/a	n/a	n/a
Medtronic Guardian™ Sensor 4 MMT-7040C1	Yes	Accessed through Local Health Office	Yes	One year
Medtronic Guardian™ Sensor 4 MMT-7040QC1	Yes	Accessed through Local Health Office	Yes	One year
Medtronic Guardian™ Sensor 3 MMT-7020C1	Yes	Accessed through Local Health Office	Yes	One year
GlucoRx Aidex™	Yes	Accessed privately from pharmacies or online from GlucoRx.co.uk	Yes	Four years

n/a: not applicable

9.2.3.2 Display devices

All of the CGM sensors submitted for review can connect with a smartphone app to view CGM readings. Some CGM sensors can also connect with a separate reader/receiver device for patients who do not have a compatible smartphone, which are offered by the suppliers free of charge or subject to a payment. An overview of these details is outlined in table 14.

Table 14: Display device information of each CGM sensor submitted

CGM sensor	Display device options	Smartphone app, website providing details of smartphone compatibility	Separate reader/receiver available	Cost associated with separate reader/receiver
Freestyle Libre 2	Smartphone app, reader	Freestyle LibreLink App, https://www.diabetescare.abbott/support/manuals/uk.html	Yes	No
Dexcom G6	Smartphone app, receiver	Dexcom G6 App, https://www.dexcom.com/en-IE/compatibility	Yes	Yes
Dexcom G7	Smartphone app, receiver	Dexcom G7 App, https://www.dexcom.com/en-IE/compatibility	Yes	Yes
Dexcom ONE+	Smartphone app, receiver	Dexcom ONE+ App, https://www.dexcom.com/en-IE/compatibility	Yes	No
Medtronic Guardian™ Sensor 4 MMT-7040C1	Smartphone app, readings displayed on insulin pump screen	MiniMed™ mobile App, https://www.medtronic-diabetes.com/en-gb/check-compatibility-app	No	n/a
Medtronic Guardian™ Sensor 4 MMT-7040QC1	Smartphone app	Guardian™ 4 App, https://www.medtronic-diabetes.com/en-gb/check-compatibility-app	No	n/a
Medtronic Guardian™ Sensor 3 MMT-7020C1	Smartphone app, readings displayed on insulin pump screen	MiniMed™ mobile App, https://www.medtronic-diabetes.com/en-gb/check-compatibility-app	No	n/a
GlucoRx Aidex™	Smartphone app	GlucoRx AiDEX™, https://www.glucorx.ie/aidex-compatibility/	No	n/a

n/a: not applicable

Further information provided by suppliers about their display devices

Abbott Diabetes Care

The Freestyle Libre 2 reader can be ordered by HCPs through an Abbott Diabetes Care Territory Manager, and can be ordered by patients who can contact Abbott Diabetes Care directly.

Dexcom

Dexcom ONE+ has the option of a receiver however this is not included automatically. The Dexcom ONE+ receiver is available at no cost for patients who are unable to access or use the smartphone app. This must be based on the prescriber's assessment of specific patient needs. The Dexcom ONE+ receiver will be distributed via Dexcom sales team upon request from a HCP. The receivers for the Dexcom G6 and Dexcom G7 have an associated cost and can be accessed via the Local Health Office.

9.2.3.3 Alerts and alarms

CGM systems offer low glucose alerts, which alert the user when their blood glucose level drops below a certain level. The aim is to prevent a hypoglycaemic or a severe hypoglycaemic episode, depending on the level that the alert is set to. CGM systems also offer high glucose alerts which alert the user when their blood glucose level rises above a certain level.[15]

All of the CGM systems submitted offer low glucose alerts and high glucose alerts as a feature, and the level they are set at can be altered according to individual preference and clinical need. Some CGM sensors also have predictive low-glucose alarms. An overview of the alerts and alarms of each CGM sensor is outlined in table 15.

Table 15: Alerts and alarms of each CGM sensor submitted

CGM sensor	High and low glucose alarms/alerts	Predictive low-glucose alarm
Freestyle Libre 2	Yes*	No
Dexcom G6	Yes	Yes
Dexcom G7	Yes	Yes
Dexcom ONE+	Yes	No
Medtronic Guardian™ Sensor 4 MMT-7040C1	Yes	Yes
Medtronic Guardian™ Sensor 4 MMT-7040QC1	Yes	Yes
Medtronic Guardian™ Sensor 3 MMT-7020C1	Yes	Yes
GlucoRx Aidex™	Yes	No

*When Freestyle LibreLink Application on a smartphone is used. The Freestyle Libre 2 reader will also issue alarms if they are turned on.

9.2.3.4 System notifications when the CGM sensor (and transmitter if applicable) are approaching expiration

CGM systems offer alerts to notify the user when the CGM sensor is approaching expiration. Some CGM systems offer a notification when the transmitter, if applicable, is approaching expiration. An overview of these notifications for each CGM sensor is outlined in table 16.

Table 16: Details of notification provided when the CGM sensor (and transmitter if applicable) are approaching expiration for each CGM sensor submitted

CGM sensor	Notification when CGM sensor is approaching expiration	Notification when transmitter is approaching expiration
Freestyle Libre 2	Yes	n/a
Dexcom G6	Yes	Yes
Dexcom G7	Yes	n/a
Dexcom ONE+	Yes	n/a
Medtronic Guardian™ Sensor 4 MMT-7040C1	Yes	Yes
Medtronic Guardian™ Sensor 4 MMT-7040QC1	Yes	Yes
Medtronic Guardian™ Sensor 3 MMT-7020C1	Yes	Yes
GlucoRx Aidex™	Yes	No

n/a: not applicable

9.2.3.5 Compatibility with other systems

Many CGM sensors are used as stand-alone devices (i.e. can operate independently of an insulin pump) to monitor glucose readings and dosing of insulin is undertaken separately. Some CGM sensors are compatible with insulin pump systems. Insulin pump systems are also known as Continuous Subcutaneous Insulin Infusion (CSII). 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[15].

Hybrid closed loop (HCL) systems involve both a CGM system and CSII system. In HCL systems, the CSII system uses an algorithm to continuously take glucose readings from a CGM system and calculate how much background insulin is needed. It then automatically delivers the insulin via an insulin pump. The system therefore automatically adjusts the background insulin delivery if glucose levels go too low or too high. With a HCL system, the individual must still control how much bolus insulin is given[15].

The compatibility of each CGM sensor submitted with CSII and HCL systems is outlined in table 17.

Table 17: Compatibility of each CGM sensor submitted with continuous subcutaneous insulin infusion or hybrid close loop systems as of June 2024

CGM sensor	Stand-alone use (i.e. can operate independently of an insulin pump)	Continuous subcutaneous insulin infusion compatibility	Hybrid closed loop compatibility
Freestyle Libre 2	Yes	No	No
Dexcom G6	Yes	Yes	Yes
Dexcom G7	Yes	Yes	Yes
Dexcom ONE+	Yes	No	No
Medtronic Guardian™ Sensor 4 MMT-7040C1	No	Yes	Yes
Medtronic Guardian™ Sensor 4 MMT-7040QC1	Yes	No	No
Medtronic Guardian™ Sensor 3 MMT-7020C1	No	Yes	No
GlucoRx Aidex™	Yes	No	No

9.2.3.6 Data sharing features

All of the CGM sensors submitted as part of the evaluation included functionality to share CGM sensor data with the patient's HCP and with others (family/friends). The details of the share mechanisms are outlined in table 18.

Table 18: Details of data sharing mechanisms for each CGM sensor submitted

CGM sensor	Data sharing with HCPs available	Data sharing with family and friends available
Freestyle Libre 2	LibreView	LibreLinkUp App
Dexcom G6	Dexcom Clarity, Glooko	Dexcom Follow App
Dexcom G7	Dexcom Clarity, Glooko	Dexcom Follow App
Dexcom ONE+	Dexcom Clarity, Glooko	Dexcom Follow App
Medtronic Guardian™ Sensor 4 MMT-7040C1	CareLink System	CareLink Connect App
Medtronic Guardian™ Sensor 4 MMT-7040QC1	CareLink System	CareLink Connect App
Medtronic Guardian™ Sensor 3 MMT-7020C1	CareLink System	CareLink Connect App
GlucoRx Aidex™	CGM viewer (www.cgmviewer.com)	https://grxaidex.com/dashboard

Recommendation

In relation to the criterion of associated system features, the MMP is of the opinion that it is preferable to have a combined sensor and transmitter and to have the option of a reader/receiver available. All CGM sensors reviewed offer high and low alarms/alerts, with varying individual

alarm/alert and notification features. The MMP is of the opinion that there is a similar offering of data sharing mechanisms available. In relation to compatibility with other systems, the MMP is of the opinion that only CGM sensors that can operate as a stand-alone CGM sensor (i.e. can operate independently of an insulin pump), should be considered for inclusion in the preferred list. CGM sensors that do not operate as a stand-alone CGM sensor should only be considered in the context of concomitant insulin pump use. It is preferable to have an option of more than one preferred CGM sensor for patients and prescribers to choose from.

9.2.4 Expenditure in the area and potential for cost efficiencies

The expenditure associated with the CGM sensors that were submitted as part of *the MMP evaluation for the identification of preferred continuous glucose monitoring sensor(s) with associated system(s)* and potential for cost efficiencies were considered under this criterion.

There has been a substantial increase in expenditure and utilisation of CGM sensors, under the CDS between January 2021 and December 2023.[12]

Total monthly expenditure (inclusive of reimbursement price, value-added tax (VAT) and pharmacy fees), on CGM sensors under the CDS, in January 2021 was approximately €1.57 million, increasing to approximately €2.45 million in January 2022, and approximately €3.77 million in January 2023. By December 2023, total monthly expenditure on CGM sensors was approximately €5.35 million.[12]

The total annual expenditure on CGM sensors under the CDS was approximately €23.78 million in 2021, increasing to approximately €35.13 million in 2022. In 2023, the total annual expenditure on CGM sensors was approximately €55.72 million.[12]

Figure 1 below illustrates the total monthly expenditure on CGM sensors under the CDS from January 2021 to December 2023.[12]

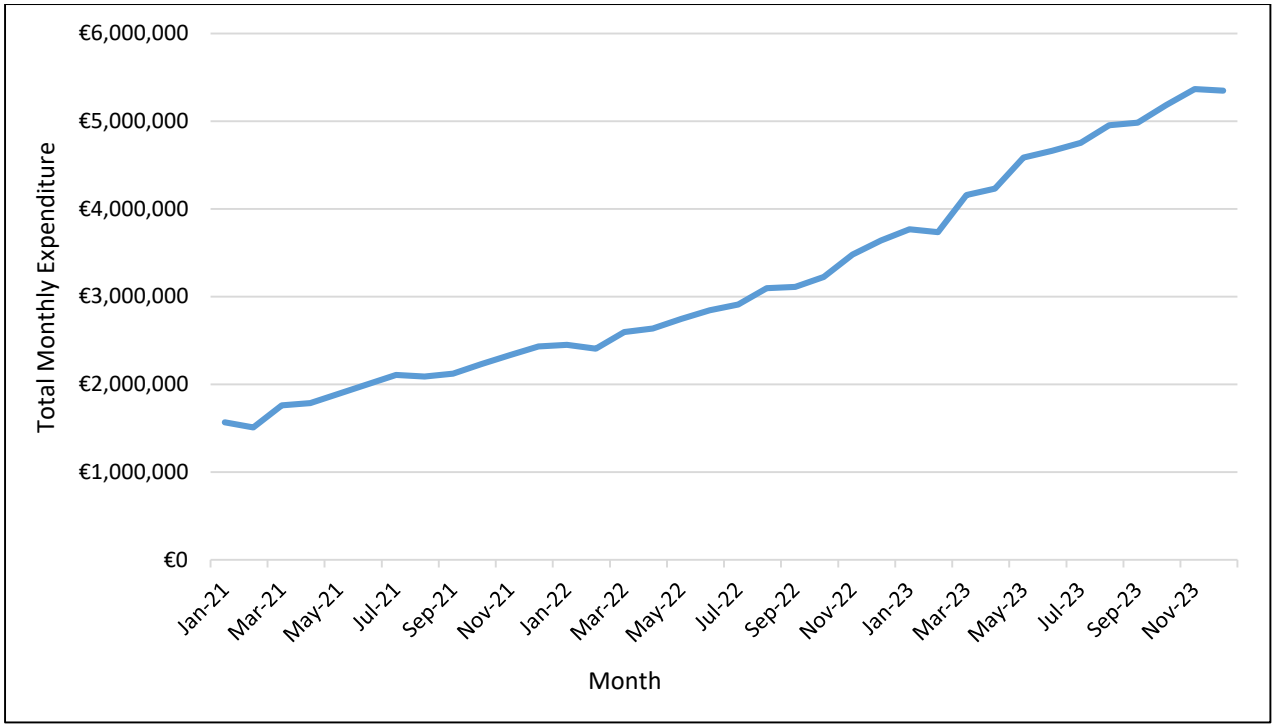

Figure 1: Total monthly expenditure on CGM sensors under the Community Drug Schemes from January 2021 to December 2023, inclusive of VAT and fees

The cost per day for each CGM sensor, as of 01/07/2024 is outlined in table 3. In 2023, CGM sensors with a cost per day of greater than or equal to €6.80 accounted for the majority of total CGM sensors expenditure in that year under the CDS. Currently, efficiencies can be achieved through prescribing and utilisation of CGM sensors with a cost per day of less than or equal to €3.16 under the CDS. Any additional savings that could have been realised through the use of CGM sensors which have a lower cost per day have not been realised.

Submissions received during the evaluation process included revised reimbursement prices for some of the CGM sensors listed in table 3, resulting in a reduction in the cost per day and annual cost to the HSE per person for certain CGM sensors, when compared with 2023.

Recommendation

In relation to the criterion of expenditure in the area and potential for cost efficiencies, the MMP is of the opinion that CGM sensors with a lower cost per day should be considered for inclusion in the preferred list of CGM sensors, once all other criteria have also been satisfied.

Currently, a cost per day of less than or equal to €3.16 captures more than one option for patients and prescribers to choose from, while also allowing for efficiencies to be generated.

9.2.5 Provision of patient support services by the supplier

The provision of patient support services by the suppliers of the CGM sensors that were submitted as part of the *MMP evaluation for the identification of preferred continuous glucose monitoring sensor(s) with associated system(s)*, was considered.

Due consideration was given to services provided by suppliers, which assist patients in using their CGM sensor with associated system, including:

- The availability of patient support materials to aid in the use of the CGM sensor with associated system, including on supplier's websites, other websites and in printed form.
- The availability of a phone line and email providing patient support including technical support.

The following sections outline contact information/details submitted by each individual supplier.

Abbott Diabetes Care (Freestyle Libre 2)
Website: www.freestyle.abbott/ie-en
Email: adchelpuk@abbott.com
Phone number: 1800 776 633 open from 8 am to 8 pm Monday to Friday and from 9 am to 5 pm on Saturdays

Dexcom (Dexcom G6, Dexcom G7, Dexcom ONE+)
Website: www.dexcom.com/en-ie
Email: ukie.orders@dexcom.com
Phone number: 1800 827 603 open from 7 am to 6 pm Monday to Friday and from 8:30 am to 4:30 pm on Saturdays

Medtronic (Medtronic Guardian™ Sensor 4 MMT-7040C1, Medtronic Guardian™ Sensor 4 MMT-7040QC1, Medtronic Guardian™ Sensor 3 MMT-7020C1)
Website: https://www.medtronic-diabetes.com/en-IE/wecare-info
Email: rs.ukdiabetesproductsupport@medtronic.com
Phone number: 01 5111 444 open 24 hours a day, 365 days a year

Windzor Pharma Ltd (GlucoRx Aidex™)
Website: https://www.glucorx.ie/cgm/
Email: info@windzorpharma.com

Phone number: 01 695 0401 available Monday to Friday, 9 am to 5 pm

Recommendation
In relation to the criterion of provision of patient support services by the supplier, the MMP is of the opinion that there is a similar offering provided by the suppliers of the submitted CGM sensors.

9.2.6 Provision of education resources to HCPs by the supplier

The provision of education resources to HCPs by suppliers of the CGM sensors that were submitted as part of the *MMP evaluation for the identification of preferred continuous glucose monitoring sensor(s) with associated system(s),* was considered.

Individuals using a CGM sensor with associated system require access to a HCP who is competent in the CGM sensors use. Therefore, due consideration was given to the education resources provided by suppliers, which aid HCPs in educating patients on the use of their CGM sensor with associated system including:

- The availability of support materials to assist in patient training.
- Access to training e.g. on site, remotely, via website resources.
- The availability of a phone line and email providing HCP support.

The following sections outline contact information/details submitted by each individual supplier.

Abbott Diabetes Care (Freestyle Libre 2)
Website: https://pro.freestyle.abbott/ie-en/home.html
Email: adchelpuk@abbott.com
Phone number: 1800 776 633 open from 8 am to 8 pm Monday to Friday and from 9 am to 5 pm on Saturdays

Dexcom (Dexcom G6, Dexcom G7, Dexcom ONE+)
Website: https://ie.provider.dexcom.com/education-and-resources
Email: ukie.orders@dexcom.com
Phone number: 1800 827 830 open from 9 am to 5:30 pm Monday to Friday

Medtronic (Medtronic Guardian™ Sensor 4 MMT-7040C1, Medtronic Guardian™ Sensor 4 MMT-7040QC1, Medtronic Guardian™ Sensor 3 MMT-7020C1)
Website: https://wepartner.medtronic-diabetes.com/en-GB

Email: rs.ukdiabetesproductsupport@medtronic.com

Phone number: 01 5111 444 open 24 hours a day, 365 days a year

Windzor Pharma Ltd (GlucoRx Aidex™)
Website: https://glucorxaidex.com/health-care-professional-hub/

Email: medical@windzorpharma.com

Phone number: 086 8243967 open from 9 am to 6 pm, 7 days a week

Recommendation
In relation to the criterion of provision of education resources to HCPs by the supplier, the MMP is of the opinion that there is a similar offering provided by suppliers of the submitted CGM sensors.

9.2.7 Robustness of supply of CGM sensor with associated system to the Irish Market

The robustness of supply of CGM sensors with associated systems to the Irish Market, as outlined by suppliers of CGM sensors that were submitted as part of the *MMP evaluation for the identification of preferred continuous glucose monitoring sensor(s) with associated system(s),* was considered.

Due consideration was also given to current and future supply of CGM sensors to the Irish Market. Information submitted by suppliers in relation to robustness of supply of CGM sensors with associated systems to the Irish Market, outlined various processes demonstrating their individual capacity to supply CGM sensors to the Irish Market.

In relation to the evidence of a supplier's capacity to meet the ongoing needs of Irish patients, the MMP considered the market share of the CGM sensors that were submitted as part of this evaluation. This analysis showed that between December 2023 and February 2024, 19,756 individuals received CGM sensors under the CDS.[12]

The supply of CGM sensors that were not submitted to this evaluation process was also considered. In the event where a supplier had submitted a CGM sensor for inclusion in this evaluation, but had omitted another CGM sensor that they had on the reimbursement list, these suppliers were then asked to provide details of the supply status in terms of availability for supply or otherwise, of such CGM sensors. Further information in relation to this process is outlined under the criterion entitled *Other relevant factors,* section 9.2.9.3.

Recommendation

In relation to the criterion of robustness of supply of CGM sensors with associated systems to the Irish Market, the MMP is of the opinion that that there is a similar offering provided by suppliers of the submitted CGM sensors. Having more than one supplier for the preferred list would mitigate potential risks from supply issues with an individual supplier.

9.2.8 Patient factors

Patient factors are closely related to a number of other criteria, including CGM sensor features, and associated system features, considered as part of the *MMP evaluation for the identification of preferred continuous glucose monitoring sensor(s) with associated system(s).*

Due consideration was given to a range of patient factors including:

- Age requirement for the CGM sensor (see table 7)
- Application site of CGM sensor (see table 8)
- Lifespan of CGM sensor (see table 10)
- Size of CGM sensor (see table 11)
- Availability of alerts and alarms (see table 15)

Recommendation

In relation to the criterion of patient factors, the MMP is of the opinion that an option of more than one preferred CGM sensor is preferable for patients and prescribers to choose from.

9.2.9 Any other relevant factors

Any other relevant factors that were appropriate to consider as part of the *MMP evaluation for the identification of preferred continuous glucose monitoring sensor(s) with associated system(s),* were included under this criterion.

Due consideration was given to:

- Submissions from HCP and patient organisations
- CGM sensor replacement
- Supply status of CGM sensors on the reimbursement list that were not submitted for evaluation.

9.2.9.1 Submissions from HCP and patient organisations

A number of submissions were received from HCP and patient organisations during the consultation process. The themes outlined in these submissions included requests that due consideration be given to the lifespan of the CGM sensor, compatibility of the CGM sensor with other devices including insulin pumps, application site, requirement for system calibration, option for data sharing with HCPs and family/friends and CGM sensor replacement.

Due consideration was given to these submissions throughout the evaluation.

9.2.9.2 CGM sensor replacement

As part of the evaluation process individual companies outlined the following information regarding CGM sensor replacement.

- **Abbott Diabetes Care (Freestyle Libre 2)**
  Abbott Diabetes Care outline that people with diabetes are asked to call the helpline, which is available by phoning 1800 776 633 open from 8 am to 8 pm Monday to Friday and from 9 am to 5 pm on Saturdays, answer a few questions and a new sensor is sent directly to their home address within 24 hours if needed.

- **Dexcom (Dexcom G6, Dexcom G7, Dexcom ONE+)**
  "Dexcom Tech Support Team are available to discuss and troubleshoot with any queries including sensor failures or any product defects on 1800 827 603. The technical support team are open Monday to Friday from 7 am to 6 pm and Saturday and Sunday from 8:30 am to 4:30 pm and can discuss trouble shooting issues and replacement sensors for individual products." "Dexcom requests all HCPs and users to contact tech support directly to request any replacement sensors."

- **Medtronic (Medtronic Guardian™ Sensor 4 MMT-7040C1, Medtronic Guardian™ Sensor 4 MMT-7040QC1, Medtronic Guardian™ Sensor 3 MMT-7020C1)**
  Patients can self-order sensor replacements through the WeCare App. Patients can also contact Medtronic via phone (01 5111 444 open 24 hours a day, 365 days a year) or email rs.ukdiabetesproductsupport@medtronic.com to request replacement sensors.

- **Windzor Pharma Ltd (GlucoRx Aidex™)**
  There is a CGM sensor replacement process in place.

9.2.9.3 Supply status of CGM sensors on the reimbursement list that were not submitted for evaluation

As part of the evaluation process, the MMP contacted suppliers who had submitted a CGM sensor as part of the *MMP evaluation for the identification of preferred continuous glucose monitoring sensor(s) with associated system(s),* to review the supply status of any other CGM sensor from that supplier that was not submitted for evaluation (i.e. if a CGM sensor on the reimbursement list was available for supply to the Irish Market but had not been submitted for evaluation).

Table 19 outlines the supply status of CGM sensors that were not submitted for evaluation, based on information provided by suppliers.

Table 19: Supply status of CGM sensors that were not submitted for evaluation

Supplier	CGM sensor	Pack size	Reimbursement code	Supply status
Abbott Diabetes Care	Freestyle Libre*	1	86900**	Currently being discontinued/phased out and not submitted for evaluation
Medtronic	Medtronic Glucose Enlite Sensor BNENSENS$^{\Upsilon}$	10	83204	Not submitted for evaluation and has subsequently been removed from the reimbursement list

*Freestyle Libre is currently being replaced by Freestyle Libre 2; **Administrative code; $^{\Upsilon}$Removed from reimbursement list by supplier on 01/05/2024

Recommendation

In relation to the criterion of other relevant factors, consideration was given to information submitted by HCP and patient organisations throughout the evaluation process. Consideration was also given to information provided by suppliers regarding CGM sensor replacement and the supply status of their CGM sensors.

10. Preferred CGM sensor(s) with associated system(s)

Following review of the submissions received in accordance with the criteria outlined in the roadmap, the MMP has identified two preferred CGM sensors with associated systems, for people with diabetes requiring CGM[iii] who are not insulin pump users. The preferred CGM sensors are outlined in List A (table 20).

Table 20: Preferred CGM sensors - List A

Preferred CGM sensors – List A		
CGM sensor	**Reimbursement code**	**Pack size**
Freestyle Libre 2	85581	1
Dexcom ONE+	97636	1

Any CGM sensor which is not on List A has been identified as a List B CGM sensor.

List B consists of CGM sensors that:

- Did not meet certain criteria as part of the *MMP evaluation for the identification of preferred continuous glucose monitoring sensor(s) with associated system(s)*

and/or

- Were not submitted for inclusion in the *MMP evaluation for the identification of preferred continuous glucose monitoring sensor(s) with associated system(s)*

Table 21: Non-preferred CGM sensors - List B

Non-preferred CGM sensors – List B		
CGM sensor	**Reimbursement code**	**Pack size**
Freestyle Libre*	86900**	1
Dexcom G6	97628	1
Dexcom G6	97629	3
Dexcom G7	97631	1
Medtronic Guardian™ Sensor 4 MMT-7040C1	97645	5
Medtronic Guardian™ Sensor 4 MMT-7040QC1	97671	5
Medtronic Guardian™ Sensor 3 MMT-7020C1	97680	5
GlucoRx Aidex™	85241	1

*Freestyle Libre is currently being replaced by Freestyle Libre 2; **Administrative code

[iii] Reimbursement is supported in accordance with Primary Care Reimbursement Service circular 033/23 Continuous Glucose Monitoring (CGM) Reimbursement Application System[13]

11. MMP recommendations

The MMP recommends a preferred CGM sensor with associated system from List A for people with diabetes* requiring CGM who are not insulin pump users, when:

- ✓ First initiating CGM
- ✓ Continuing CGM upon review
- ✓ Changing CGM sensor with associated system

*Reimbursement is supported in accordance with Primary Care Reimbursement Service circular 033/23 Continuous Glucose Monitoring (CGM) Reimbursement Application System[13]

Initiating CGM

When initiating CGM, the HCP should first assess individual requirements. If CGM is recommended without the use of an insulin pump, the HCP should aim to use a CGM sensor from **LIST A** that best suits the individual's needs.

Reviewing CGM

When reviewing CGM, the HCP should first assess individual requirements. If ongoing CGM without the use of an insulin pump is recommended on review, the HCP should aim to use a CGM sensor from **LIST A** that best suits the individual's needs.

Changing CGM sensors

When changing a CGM sensor, the HCP should first assess individual requirements. If ongoing CGM without the use of an insulin pump is recommended on review, the HCP should aim to use a CGM sensor from **LIST A** that best suits the individual's needs.

Implementation of the preferred CGM sensors will lead to significant savings for the HSE, in the order of millions of euros.

For people with diabetes requiring CGM who are not insulin pump users:

Choose a CGM sensor from List A when initiating or changing CGM.

Do not choose a CGM sensor from List B when initiating or changing CGM, unless clinically justified.

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13. Appendices

Appendix A: HSE-MMP roadmap for the identification of preferred continuous glucose monitoring sensor(s) with associated system(s)

Continuous glucose monitoring (CGM) systems provide an alternative approach to using blood glucose test strips for self-monitoring of blood glucose, by measuring glucose levels in the interstitial fluid (a thin layer of fluid around the cells). These systems comprise of sensors (self-administered subcutaneously, typically in the upper arm and replaced every 7 to 14 days depending on the system), transmitters (or combined sensors and transmitters), and a mechanism to display the results (readers/receivers or smart device application). There are two types of CGM systems; real-time CGM (rtCGM) and intermittently scanned CGM (isCGM).

Patients can access CGM sensors under the Community Drug Schemes (CDS), as they are included on the Health Service Executive-Primary Care Reimbursement Service (HSE-PCRS) list of reimbursable items.

For CGM sensors to be included on the list of reimbursable items, they must have satisfied the certification process, as outlined in the *HSE-PCRS Personal Diagnostic, Monitoring and Delivery Devices Guidelines for Suppliers*, at the time of their application. This process is underpinned by the Health (Pricing and Supply of Medical Goods) Act 2013. The Health Products Regulatory Authority (HPRA) has a regulatory role involving the monitoring of medical devices (e.g. CGM sensors) in Ireland including operating a national reporting system for medical devices.

According to MMP analysis*, there has been an increase in utilisation and total expenditure on CGM sensors, under the CDS over the last two years. The number of patients in receipt of CGM sensors under the CDS on a monthly basis between January 2021 and December 2022, increased from approximately 6,000 to 12,400, while total monthly expenditure increased from approximately €1.57 million to €3.64 million. Total expenditure on CGM sensors under the CDS in 2022 was estimated by the MMP to be approximately €35 million. Utilisation and expenditure on CGM sensors has accelerated during 2023. In August 2023, the MMP estimated total monthly expenditure on CGM sensors to be approximately €4.95 million, with approximately 15,900 individuals in receipt of a CGM sensor under the CDS.

Rapid Health Technology Assessment

The Health Information and Quality Authority (HIQA) *Rapid Health Technology Assessment of Continuous Glucose Monitoring in Adults with Type 1 Diabetes Mellitus* was published on 29th September 2023. This assessment includes a number of recommendations and advice points, the following of which are relevant to this roadmap:

- Switching to an economically advantageous CGM system, when clinically appropriate to do so, may result in cost savings for the HSE.
- Given the higher cost of the rtCGM systems and limited evidence to demonstrate their benefit over and above isCGM devices, a consideration would be whether those currently on rtCGM systems be switched to isCGM.

Evaluation Process

The MMP will undertake an evaluation to identify preferred CGM sensor(s) with associated system(s) to support safe, effective and cost-effective prescribing in Ireland. The MMP will publish an evaluation document for the use of the preferred CGM sensor(s) with associated system(s). A collaborative

approach involving clinicians, nurses, pharmacists, patients and the health service will be required to implement utilisation of the preferred CGM sensor(s) with associated system(s).

A number of criteria may be considered by the MMP in identifying the preferred CGM sensor(s) with associated system(s), including:

1. Acquisition cost of the CGM sensor
2. CGM sensor features
3. Associated system features (and acquisition costs if applicable)
4. Expenditure in the area and potential for cost efficiencies
5. Provision of patient support services by the supplier
6. Provision of education resources to healthcare professionals by the supplier
7. Robustness of supply of CGM sensor with associated system to the Irish Market
8. Patient factors
9. Any other relevant factors (e.g. requirement for calibration with blood glucose test strips).

Work Plan

The MMP will commence work on the identification of the preferred CGM sensor(s) with associated system(s), using the process as outlined in this roadmap. This includes a consultation period where submissions are invited from all relevant stakeholders, including the suppliers of CGM sensors with associated systems. This process will be limited to CGM sensors on the HSE-PCRS list of reimbursable items, or those that are the subject of an application for addition to the list of reimbursable items submitted to the HSE by close of business on 8th November 2023. In addition, the CGM sensor and associated system must be available for supply to the Irish market.

Submissions can be emailed to mmp@hse.ie. Alternatively, the MMP can provide access to a secure file transfer system for submissions, please contact the MMP for further details. The MMP will issue confirmation of receipt of submission within 72 hours. Please contact the MMP if you do not receive confirmation of receipt after this time.

The consultation period will open on 9th November 2023. The closing date for submissions is 7th December 2023 at 1pm.

References

1. Health Information and Quality Authority. Rapid Health Technology Assessment of Continuous Glucose Monitoring in Adults with Type 1 Diabetes Mellitus. September 2023. Available: https://www.hiqa.ie/reports-and-publications/health-technology-assessment/rapid-health-technology-assessment-continuous
2. HSE-Primary Care Reimbursement Service (HSE-PCRS) list of reimbursable items Available: https://www.hse.ie/eng/staff/pcrs/items/
3. PCRS database analysis – Utilisation and total expenditure on CGM sensors. On file.
4. HSE-Primary Care Eligibility and Reimbursement Service. Personal Diagnostic, Monitoring & Delivery Devices Guidelines for Suppliers. March 2022. Available: https://www2.healthservice.hse.ie/organisation/national-pppgs/personal-diagnostic-monitoring-delivery-devices-guidelines-for-suppliers/

Appendix B: Identification of preferred continuous glucose monitoring sensor(s) with associated system(s): Cover Page for Submissions

For all submissions relating to a particular continuous glucose monitoring (CGM) sensor, section A must be completed and included as the cover page for the submission. All CGM sensors included in the submission must be listed in the table below, along with information relating to the accompanying systems (associated transmitters and readers/receivers, where relevant).

In addition, suppliers of CGM sensors must also complete section B, and include as the cover page for the submission.

Section A:

CGM sensor name	**PCRS reimbursement code**	Accompanying systems (include information in relation to associated transmitters and readers/receivers, where relevant)

HSE-Primary Care Eligibility and Reimbursement Service. Personal Diagnostic, Monitoring & Delivery Devices Guidelines for Suppliers. March 2022. Available: https://www2.healthservice.hse.ie/organisation/national-pppgs/personal-diagnostic-monitoring-delivery-devices-guidelines-for-suppliers/

Section B:

I, the undersigned, confirm compliance with:

- *Applicable national standards and European Commission standards*
- *All applicable laws*

For all products (CGM sensors and accompanying systems) listed in the table in section A above.

Managing Director Signature: _____

Managing Director Name: _____

Company name: _____

Date of submission: _____

Submissions can be emailed to mmp@hse.ie. Alternatively, the MMP can provide access to a secure file transfer system for submissions, please contact the MMP for further details. The MMP will issue confirmation of receipt of submission within 72 hours. Please contact the MMP if you do not receive confirmation of receipt after this time.