Feidhmeannacht na Seirbhíse Sláinte, Seirbhís Aisíocaíochta Cúraim Phríomhúil
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Peter 'Chap' Cleere, T.D.
Dáil Éireann,
Leinster House,
Kildare Street,
Dublin 2.

18th March 2025

PQ: 9647/25

To ask the Minister for Health the reason buscopan RX has been removed from the general medical scheme/medical card scheme; and if she will make a statement on the matter. -Peter 'Chap' Cleere

Dear Deputy Cleere,

The Health Service Executive has been requested to reply directly to you in the context of the above Parliamentary Question (Reference 9647/25), which you submitted to the Minister for Health for response.

Products are added to the Reimbursement List in line with the Health (Pricing and Supply of Medical Goods) Act 2013. Marketing Authorisation Holders are required make formal pricing and reimbursement application to the HSE under the legislation.

Whilst the HSE would actively engage with companies regarding the reasons for withdrawing from the Reimbursement List and seek to address insofar as it can, the decision lies with the Market Authorisation Holder who may for commercial reasons withdraw a product from Community Drug Schemes.

The HSE PCRS can confirm that the Marketing Authorisation Holder for Buscopan® has submitted a discontinuation notification form to the HSE for withdrawal of the product from the Reimbursement List. The Marketing Authorisation Holder has stated that Buscopan® 10 mg (hysocine butylbromide 56 tablets – dispensing pack) has been withdrawn from the Irish market as the manufacturer is no longer able to supply the product.

Applications for reimbursement support of hyoscine butylbromide 10 mg tablets will be considered for medical card holders under Discretionary Hardship Arrangements.

Yours sincerely,

Suzanne Doyle
Primary Care Reimbursement Service

The Health Service Executive operates the General Medical Services Scheme, which includes Medical Cards and GP Visit Cards, under the Health Act 1970, as amended. It has established a dedicated contact service for members of the Oireachtas specifically for queries relating to the status of Medical Cards and GP Visit Cards applications, which the Deputy / Senator may wish to use for an earlier response. Tel: 01-8647180 / email: Oireachtas.pcrs@hse.ie

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29th November 2023

Circular 033/23

RE: Continuous Glucose Monitoring (CGM) Reimbursement Application System

Dear Pharmacist,

Further to Circular 28/23, a single reimbursement application system for Continuous Glucose Monitoring (CGM) sensors will come into effect on 1st December 2023. Due to the budget impact associated with these products, the HSE has established a single reimbursement application system for all CGM sensors on the Reimbursement List. This reimbursement application system will apply to any future CGM sensors reimbursed under Community Drug Schemes. This system also replaces the current application system in place for FreeStyle Libre 1 (Flash Glucose Monitoring) sensors.

The reimbursement application system is confined to those hospital clinicians responsible for the initiation of CGM systems for individuals with Type 1 Diabetes Mellitus. Reimbursement support of these products has not been extended to any other patient cohort. All applications will be reviewed by the HSE Medicines Management Programme.

Approval can be confirmed through the online Secure Schemes Checker under 'Patient Specific Arrangements' from 1st December 2023. Pharmacies can dispense and claim for CGM sensors electronically using the individual GMS codes for the product, submitting in the normal manner with monthly claims. Claims submitted for patients who are not approved will not be paid.

Patients treated with insulin who have recently accessed a CGM sensor under Community Drug Schemes will continue to have reimbursement support. Approval of these patients will be visible on the Secure Scheme Checker and an application through the new application system will not be required where approval is in place. This includes those currently approved for FreeStyle Libre 1 sensors. From 1st December 2023, all patients newly initiated on CGM sensors must receive prior approval for reimbursement support.

The list of CGM sensors and the annual maximum reimbursable quantity for each individual sensor type is outlined below. Maximum quantities will differ due to sensors having variable wear times. Reimbursement will not be supported for higher quantities than the maximum outlined below.

GMS Code	CGM Sensor Name	Pack Size	Maximum Annual Reimbursed Quantity	Wear Time per Sensor
97628	Dexcom G6	1	39 packs	10 days
97629	Dexcom G6	3	13 packs	10 days
97631	Dexcom G7	1	39 packs	10 days*
86900	FreeStyle Libre 1	1	26 packs	14 days
85581	FreeStyle Libre 2	1	26 packs	14 days
85241	GlucoRx Aidex	1	26 packs	14 days
99962	Medtronic Guardian 4 BNUIG4SCGM10	10	6 packs	7 days

99963	Medtronic Guardian 4 BNUIG4SMDI10	10	6 packs	7 days
94169	Medtronic Guardian 3 BNGLGSENS310	10	6 packs	7 days
83204	Medtronic Glucose Enlite BNENSENS	10	7 packs	6 days

*+12 hour grace period

There are two additional products reimbursed under this arrangement effective 1st December 2023– FreeStyle Libre 2 CGM sensors and GlucoRx Aidex CGM sensors.

In the event that a replacement sensor is required outside the normal wear periods, patients should be advised to contact the individual company to organise a replacement in line with their sensor replacement policies.

Frequently asked questions are enclosed to support Healthcare Professionals.

Your cooperation with this important HSE initiative is appreciated.

Yours faithfully,

Shaun Flanagan
Primary Care Eligibility & Reimbursement

Continuous glucose monitoring (CGM) sensors reimbursement

Questions and Answers for Healthcare Professionals

1. **What is a CGM system and what is it used for?**

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).

2. **What changes are being made to the reimbursement of CGM sensors?**

The HSE is establishing a single reimbursement application system for all CGM sensors on the reimbursement list. This reimbursement application system will apply to all current and any future CGM sensors reimbursed under the Community Drug Schemes.

This online reimbursement application system will replace the current reimbursement application system that is in place for FreeStyle Libre 1.

If hospital clinicians wish to initiate CGM for a patient who has not recently been dispensed a CGM sensor, they will be required to submit an online application for reimbursement approval. All applications will be reviewed by the HSE Medicines Management Programme.

Reimbursement support for CGM sensors under the Community Drug Schemes is for patients with type 1 diabetes mellitus only regardless of age. Reimbursement support for these products has not been extended to any other patient cohort.

3. **Why are the HSE introducing changes to the reimbursement of CGM sensors?**

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. The published document can be found at:

https://www.hiqa.ie/reports-and-publications/health-technology-assessment/rapid-health-technology-assessment-continuous

In line with the advice from HIQA and due to the budget impact associated with CGM sensors the HSE are implementing the changes outlined above.

4. When will these changes to the reimbursement of CGM sensors be introduced?

These changes to the reimbursement of CGM sensors will be introduced on 1st December 2023. From this date, all patients initiating on CGM sensors must receive prior approval for reimbursement support.

5. Who can apply for reimbursement approval for CGM sensors?

Hospital clinicians responsible for the initiation of CGM systems (i.e., clinicians in diabetes clinics) will have access to apply for reimbursement approval for suitable patients with type 1 diabetes mellitus.

6. How can an online application be submitted?

Applications for individual reimbursement approval of CGM sensors must be submitted by the clinician responsible for the initiation of the CGM system, through the HSE Primary Care Reimbursement Service (PCRS) Special Drug Request online reimbursement application system. The CGM sensors online reimbursement application system will be available through the PCRS website www.pcrs.ie [*PCRS Online Services> Services for Hospitals> CGM Sensor Reimbursement Application*].

Clinicians must be user-registered with the HSE PCRS to apply. The *Special Drug Request Reimbursement - User Registration Form* is available on the PCRS website (www.pcrs.ie > Online Services > Services for Hospitals). Completed registration forms can be submitted to cert.info@hse.ie. Once authorised, the user will be issued with a username and password.

For clinicians who had access to submit online reimbursement applications for Freestyle Libre, this access will be transferred to the new CGM sensor online reimbursement application system.

7. **How will a pharmacist check if a patient is approved for reimbursement of a CGM sensor?**

Patient specific approval will be visible on the Secure Scheme Checker for pharmacists under "Patient Specific Arrangements".

8. **How will patients who are already accessing a CGM sensor under the Community Drug Schemes be managed?**

Patients using insulin who have recently accessed a CGM sensor under Community Drug Schemes will continue to have reimbursement support.

Approval of these patients will be visible on the Secure Scheme Checker and an application through the new online reimbursement application system will not be required where approval is in place. This includes those patients currently approved for FreeStyle Libre 1 sensors.

9. **What CGM sensors are currently on the reimbursement list?**

The following CGM sensors are available on the reimbursement list as of 1st December 2023:

GMS Code	CGM Sensor Name	Pack Size
97628	Dexcom G6	1
97629	Dexcom G6	3
97631	Dexcom G7	1
85241	GlucoRx Aidex	1
86900	FreeStyle Libre 1	1
85581	FreeStyle Libre 2	1
99962	Medtronic Guardian 4 BNUIG4SCGM10	10
99963	Medtronic Guardian 4 BNUIG4SMDI10	10
94169	Medtronic Guardian 3 BNGLGSENS310	10
83204	Medtronic Glucose Enlite BNENSENS	10

10. Is the reimbursement approval for a specific CGM sensor?

The reimbursement approval is for the use of any one of the CGM sensors that are available on the reimbursement list as of 1st December 2023.

The HSE MMP is currently undertaking an evaluation of all available CGM sensors with the aim to identify a preferred CGM sensor(s) in the coming months.

11. How will claims for CGM sensors be processed?

Pharmacies can dispense and claim for CGM sensors electronically using the individual GMS codes for the product, submitting in the normal manner with monthly claims.

12. Who do I contact in relation to reimbursement queries for CGM sensors?

The HSE PCRS should be contacted at the following email address: pharmacy.response@hse.ie

13. Who do I contact in relation to an individual reimbursement application that has been submitted?

The HSE MMP should be contacted at the following email address: mmp@hse.ie