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Pádraig Mac Lochlainn, T.D. Dáil Éireann, Leinster House, Kildare Street, Dublin 2.

15th April 2025

PQ: 14870/25

To ask the Minister for Health the number of continuous glucose monitor applications submitted for people with Type 2 diabetes, by county, by HSE regional health area, by hospital, from 1 December 2023 to 31 December 2024; the number of these applications that were successful; the number of these applications that were unsuccessful; the number appealed; the number successful following appeal; and if she will make a statement on the matter. -Pádraig Mac Lochlainn

Dear Deputy Mac Lochlainn,

The Health Service Executive has been requested to reply directly to you in the context of the above Parliamentary Question (Reference 14870/25), which you submitted to the Minister for Health for response.

The HSE has statutory responsibility for pricing and reimbursement decisions under the Community Drug Schemes, in accordance with the Health (Pricing and Supply of Medical Goods) Act 2013. In making a relevant reimbursement decision, the HSE is required under the Act to have regard to a number of criteria including the clinical efficacy, the health needs of the public, cost effectiveness, and potential or actual budget impact.

Continuous glucose monitoring (CGM) systems provide an alternative approach to self-monitoring of blood glucose (using blood glucose test strips with an associated blood glucose meter). These CGM systems comprise of sensors, transmitters and a mechanism to display the results (readers/receivers or smart device application).

According to HSE-Medicines Management Programme (MMP) analysis, there has been an increase in utilisation and total expenditure on CGM sensors, under the Community Drug Schemes. The number of individuals in receipt of CGM sensors under the Community Drug Schemes 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 Community Drug Schemes in 2023 was estimated by the MMP to be approximately ≤ 55.7 million. The Health Information and Quality Authority (HIQA) Rapid Health Technology Assessment (HTA) of Continuous Glucose Monitoring (CGM) in Adults with Type 1 Diabetes Mellitus was published on 29th September 2023. The published document can be found at: <u>Rapid Health Technology Assessment of Continuous Glucose Monitoring in Adults with Type 1 Diabetes Mellitus | HIQA</u>

In line with the advice from HIQA and due to the budget impact associated with CGM sensors, the HSE established a single reimbursement application system for all CGM sensors on the reimbursement list on 1st December 2023.

Reimbursement support for CGM sensors at this point in time is based on the HIQA HTA and is for patients with type 1 diabetes mellitus regardless of age, who have required insulin from the outset.

An application for reimbursement support of CGM sensors can be submitted for any patient, and each application is reviewed by the HSE-Medicines Management Programme (MMP) on a case-by-case basis. The single national reimbursement application system and central assessment of applications ensures that there is equitable application of the reimbursement criteria for CGM sensors.

Below is a summary of the outcomes of applications received for reimbursement support for CGM sensors between 1 December 2023 and 31 December 2024.

Total number of applications	4,813
Applications approved	3,165 (66%)
Applications rejected	917 (19%)
Applications returned or previously approved*	732 (15%)

The information provided in this table is accurate as of 25/03/2025. *This category includes applications returned requesting additional information to inform a reimbursement recommendation, and applications submitted for patients with prior approval for CGM sensors.

A breakdown of the monthly number of applications received and the outcome of the application is provided below.

Applications	Dec -23	Jan -24	Feb -24	Mar -24	Apr -24	May -24	Jun -24	Jul- 24	Aug -24	Sep -24	Oct -24	Nov -24	Dec -24
Number of applications	389	445	451	392	385	418	330	38 6	338	340	344	334	261
Number approved	210	256	288	263	272	292	225	26 3	218	229	233	226	190
Number rejected	102	106	65	74	61	74	60	72	72	74	58	56	43
Number pending	0	0	0	0	0	0	0	0	0	0	0	0	0
Number returned or previously approved	77	83	98	56	52	52	45	51	48	37	53	52	28

Due to the formatting of the captured data, and significant number of applications received, it is not feasible to analyse the number of applications received by disease type. The application data is not available by county, regional health area, hospital site.

In the 13 months of operation of the reimbursement application system up to 31 December 2024, 3,165 patients have been approved for reimbursement support for CGM sensors. This represents an additional investment by the HSE of approximately €9.7 million across the first full year of reimbursement support for these patients.

The number of patients accessing CGM sensors continues to increase since the introduction of the reimbursement application system. In December 2024 (latest data available), 19,861 patients accessed a CGM sensor under the Community Drug Schemes.

To date, a HTA of CGM sensors for people with type 2 diabetes mellitus has not been undertaken. Therefore, there is limited information to support the extension of reimbursement to this cohort, including cost-effectiveness assessment and budget impact of same. As outlined in the HSE-Primary Care Reimbursement Service (PCRS) Statistical Analysis of Claims and Payments 2023, there were 167,118 people accessing Long Term Illness (LTI) Scheme core list F, diabetes mellitus in that year. Based on current utilisation and expenditure, the HSE-MMP notes that the annual cost of the most commonly used CGM sensors range from approximately $\leq 1,500$ to $\leq 3,000$ per person per year. Based on this, there is likely to be a significant additional cost associated with the extension of reimbursement support to people with type 2 diabetes mellitus. It is estimated that the cost of extending reimbursement eligibility for CGM sensors to all people in receipt of insulin under the Community Drug Schemes for one year would be in the region of ≤ 120 million.

Appeals

Appeals to reimbursement recommendations for CGM sensors can be submitted by clinicians, and are reviewed on a case-by-case basis, reviewing the information provided in the initial online application and the information in the appeal submission to the MMP. The final reimbursement recommendation is communicated back to the clinician via email or the online application system.

A summary of appeals against reimbursement recommendations for CGM sensors between 1 December 2023 and 31 December 2024, and the outcomes of the appeals, is provided below. Appeals data is not available by disease type, county, regional health area, hospital site.

Number of appeals	200
Number of approved appeals	67
Number of rejected appeals	132
Number of pending appeals	1

The MMP have undertaken an evaluation to identify preferred CGM sensor(s) with associated system(s). This evaluation was published on 19th July 2024. This review included consideration of submissions from relevant stakeholders, including the suppliers of the CGM sensors, healthcare professional organisations and patient organisations.

https://www.hse.ie/eng/about/who/cspd/medicines-management/glucose-monitoring/preferred-cgm-sensors/

Following identification of preferred CGM sensors, the MMP is now undertaking a communication process which includes engagement with the HSE-Senior Leadership, the National Clinical Programme for Diabetes and meetings with diabetes healthcare professionals. The MMP are currently monitoring prescribing changes and uptake of the preferred products, to consider appropriate mechanisms to facilitate utilisation of the preferred products. This process will allow prescribers and diabetes centres the opportunity to implement the preferred CGM guidance into their practice

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