HSE-Medicines Management Programme (MMP)

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).

* Utilisation and total expenditure are based on data from all age groups. Total expenditure includes ingredient cost and VAT, where applicable, based on claims submitted by pharmacists.

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/