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Conor Sheehan, T.D.
Dáil Éireann,
Leinster House,
Kildare Street,
Dublin 2.

13th June 2025

PQ: 28848/25

To ask the Minister for Health if weight-loss drugs such as ozempic and mounjaro will be made available to medical card patients; her views on whether they should; and if she will make a statement on the matter. -Conor Sheehan

Dear Deputy Sheehan,

The Health Service Executive has been requested to reply directly to you in the context of the above Parliamentary Question (Reference 28848/25), which you submitted to the Minister for Health for response.

The HSE is committed to providing access to as many medicines as possible, in as timely a fashion as possible, from the resources available (provided) to it.

The HSE robustly assesses applications for pricing and reimbursement to make sure that it can stretch available resources as far as possible and to deliver the best value in relation to each medicine and ultimately more medicines to Irish citizens and patients.

HSE decisions on which medicines are reimbursed by the taxpayer are made on objective, scientific and economic grounds.

There are formal processes which govern applications for the pricing and reimbursement of medicines, and new uses of existing medicines, to be funded and / or reimbursed.

The HSE considers the following criteria prior to making any decision on pricing / reimbursement, in line with the Health (Pricing and Supply of Medical Goods) Act 2013:
(1) The health needs of the public,
(2) The cost effectiveness of meeting health needs by supplying the item concerned rather than providing other health services,

(3) The availability and suitability of items for supply or reimbursement,
(4) The proposed costs, benefits, and risks of the item or listed item relative to therapeutically similar items or listed items provided in other health service settings and the level of certainty in relation to the evidence of those costs, benefits and risks,
(5) The potential or actual budget impact of the item or listed item,
(6) The clinical need for the item or listed item,
(7) The appropriate level of clinical supervision required in relation to the item to ensure patient safety,
(8) The efficacy (performance in trial), effectiveness (performance in real situations) and added therapeutic benefit against existing standards of treatment (how much better it treats a condition than existing therapies) and,
(9) The resources available to the HSE.

In terms of the specific details of the application for pricing and reimbursement of tirzepatide (Mounjaro®):

Type 2 diabetes mellitus

The HSE received an application for pricing and reimbursement of tirzepatide (Mounjaro®) on the 24th January 2024 from Eli Lilly (the applicant) for the treatment of adults with insufficiently controlled type 2 diabetes mellitus as an adjunct to diet and exercise: as monotherapy when metformin is considered inappropriate due to intolerance or contraindications, or in addition to other medicinal products for the treatment of diabetes.

- The first step in the process is the submission of a Rapid Review dossier (a clinical and economic dossier) to the National Centre for Pharmacoeconomics (NCPE) for assessment. The HSE commissioned the Rapid Review process on the 24th January 2024.
- The NCPE Rapid Review assessment report was received by the HSE on the 6th February 2024. A full health technology assessment (HTA) was recommended to assess the clinical effectiveness and cost effectiveness of tirzepatide (Mounjaro®) compared with the current standard of care.
- The HSE commissioned a full HTA on the 1st March 2024 as per agreed processes.
- The NCPE publishes details of medicines where the HSE has commissioned a Rapid Review assessment and / or a full health technology assessment on their website. The website is updated at regular intervals and includes assessment outcomes and updates on reimbursement for each individual medicine and indication listed. Details of the assessment(s) of tirzepatide (Mounjaro®) for Type 2 diabetes mellitus are available at: Tirzepatide (Mounjaro®). HTA ID: 24003 | National Centre for Pharmacoeconomics
- The HSE Corporate Pharmaceutical Unit (CPU) is the interface between the HSE and the Pharmaceutical Industry in relation to medicine pricing and reimbursement applications.
- The Drugs Group is the national committee which the HSE has in place to make recommendations on the pricing and reimbursement of medicines. The membership of the HSE Drugs Group includes public interest members. Pharmacoeconomic reports are reviewed by the HSE Drugs Group along with the outputs of commercial negotiations, and any patient group submission(s) received. The HSE Drugs Group considers all of the evidence and makes a recommendation to the HSE Senior Leadership Team.
- The decision making authority in the HSE is the HSE Senior Leadership Team. The HSE Senior Leadership Team decides on the basis of all the demands it is faced with (across all services) whether it can fund a new medicine, or new use of an existing medicine, from the resources that have been provided to it in line with the Health (Pricing and Supply of Medical Goods) Act 2013.

Weight management

The HSE received an application for pricing and reimbursement of tirzepatide (Mounjaro®) on the 24th June 2024 from Eli Lilly (the applicant) indicated as an adjunct to a reduced-calorie diet and increased physical activity for weight management, including weight loss and weight maintenance, in adults with an initial Body Mass Index (BMI) of ≥ 30 kg/m^2 (obesity) or ≥ 27 kg/m^2 to < 30 kg/m^2 (overweight) in the presence of at least one weight-related comorbid condition (e.g., hypertension, dyslipidaemia, obstructive sleep apnoea, cardiovascular disease, prediabetes, or type 2 diabetes mellitus).

- The first step in the process is the submission of a Rapid Review dossier (a clinical and economic dossier) to the National Centre for Pharmacoeconomics (NCPE) for assessment. The HSE commissioned the Rapid Review process on the 24th June 2024.
- The NCPE Rapid Review assessment report was received by the HSE on the 30th July 2024. A full HTA was recommended to assess the clinical effectiveness and cost effectiveness of tirzepatide (Mounjaro®) compared with the current standard of care.
- The HSE commissioned a full Health Technology Assessment (HTA) on the 27th August 2024 as per agreed processes.
- The NCPE publishes details of medicines where the HSE has commissioned a Rapid Review assessment and / or a full health technology assessment on their website. The website is updated at regular intervals and includes assessment outcomes and updates on reimbursement for each individual medicine and indication listed. Details of the assessment(s) of tirzepatide (Mounjaro®) for weight management are available at: Tirzepatide (Mounjaro®). HTA ID: 24024 | National Centre for Pharmacoeconomics
- The HSE Corporate Pharmaceutical Unit (CPU) is the interface between the HSE and the Pharmaceutical Industry in relation to medicine pricing and reimbursement applications.
- The Drugs Group is the national committee which the HSE has in place to make recommendations on the pricing and reimbursement of medicines. The membership of the HSE Drugs Group includes public interest members. Pharmacoeconomic reports are reviewed by the HSE Drugs Group along with the outputs of commercial negotiations, and any patient group submission(s) received. The HSE Drugs Group considers all of the evidence and makes a recommendation to the HSE Senior Leadership Team.
- The decision making authority in the HSE is the HSE Senior Leadership Team. The HSE Senior Leadership Team decides on the basis of all the demands it is faced with (across all services) whether it can fund a new medicine, or new use of an existing medicine, from the resources that have been provided to it in line with the Health (Pricing and Supply of Medical Goods) Act 2013.

Both applications remain under consideration with the HSE. The HSE cannot make any comment on possible outcomes from the ongoing process.

In terms of the specific details of the application for pricing and reimbursement of semaglutide (Ozempic®):

Reimbursement approval is in place for semaglutide (Ozempic®) for the treatment of adults with insufficiently controlled type 2 diabetes mellitus as an adjunct to diet and exercise as monotherapy when metformin is considered inappropriate due to intolerance or contraindications and in addition to other medicinal products for the treatment of diabetes under the General Medical Services and Long Term Illness Scheme from 1st September 2018.

Pharmaceutical companies are required to submit formal applications to the HSE if they wish their medicines to be added to the list of reimbursable items covered under community drugs schemes and arrangements / funded via hospitals. In order to submit a formal application, the medicine must hold a marketing authorisation. The European Medicines Agency (EMA) is a centralised agency of the European Union (EU) responsible for the scientific evaluation, supervision and safety monitoring of medicines in the EU. The EMA plays an integral role in the authorisation of medicines in the EU via the centralised procedure. The Health Products Regulatory Authority (HPRA) is the competent authority responsible for the regulation of human medicines in Ireland. A company can submit an application for a marketing authorisation directly to the HPRA if the product in question is not required to be approved through the centralised procedure. To date neither the EMA nor the HPRA have granted marketing authorisation for semaglutide (Ozempic®) for the indication of weight management. As outlined above, the national assessment and decision process cannot commence in the absence of a marketing authorisation.

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