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Colm Burke, T.D.
Dáil Éireann,
Leinster House,
Kildare Street,
Dublin 2.

22nd September 2025

PQ: 44817/25

To ask the Minister for Health if she will confirm that a product (Wegovy) will be placed under the Health Service Executive reimbursable items list so that persons under this scheme can avail of a 2.4mg maximum dosage compared to another product (Ozempic) where the maximum dose is 1mg and is only reimbursed for the treatment of diabetes; and if she will make a statement on the matter. -Colm Burke

Dear Deputy Burke,

The Health Service Executive has been requested to reply directly to you in the context of the above Parliamentary Question (Reference 44817/25), 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 applications for pricing and reimbursement of semaglutide (Wegovy®):

Adult patients:

The HSE received a complete application for pricing and reimbursement of semaglutide (Wegovy®) on the 19th March 2025 from Novo Nordisk (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 $\geq 30 \text{ kg/m}^2$ (obesity), or $\geq 27 \text{ kg/m}^2$ to $< 30 \text{ kg/m}^2$ (overweight) in the presence of at least one weight-related comorbidity e.g. dysglycaemia (prediabetes or type 2 diabetes mellitus), hypertension, dyslipidaemia, obstructive sleep apnoea or cardiovascular disease.

- 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 21st March 2025.
- The NCPE Rapid Review assessment report was received by the HSE on the 14th May 2025. The NCPE have advised the HSE that a full health technology assessment (HTA) is recommended to assess the clinical effectiveness and cost effectiveness of semaglutide (Wegovy®) compared with the current standard of care.
- The HSE commissioned a full HTA on the 29th May 2025 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 semaglutide (Wegovy®) for adult patients are available at: <https://www.ncpe.ie/semaglutide-wegovy-hta-id-25024/>.
- 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.

Further information on the progress of semaglutide (Wegovy®) for adult patients through the HSE assessment and approval processes is available via the Pricing and Reimbursement Application tracker available at <https://www.hse.ie/eng/about/who/cpu/> . HSE application ID HSE100033 has been assigned to this application.

Adolescent patients:

The HSE received a complete application for pricing and reimbursement of semaglutide (Wegovy®) on the 19th March 2025 from Novo Nordisk (the applicant) indicated as an adjunct to a reduced-calorie diet and increased physical activity for weight management in adolescents ages 12 years and above with obesity (Body Mass Index (BMI) $\geq 95^{\text{th}}$ percentile as defined on sex and age-specific BMI growth charts) and body weight above 60 kg. The applicant is seeking reimbursement in a subpopulation of the licensed adolescent population, specifically:

- adolescent patients between the ages 12 and 17 years (inclusive) with a body weight above 60kg,
- with a BMI $> 99.6^{\text{th}}$ percentile,
- and two or more of the comorbidities as defined by Children's Health Ireland (CHI) complex obesity referral form criteria.

- 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 21st March 2025.
- The NCPE Rapid Review assessment report was received by the HSE on the 1st May 2025. The NCPE have advised the HSE that a full HTA is not recommended. The NCPE recommends that semaglutide not be considered for reimbursement at the submitted price.
<https://www.ncpe.ie/semaglutide-2-4-mg-wegovy-in-adolescent-patients-hta-id-25025/> .
- 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 CPU met with Novo Nordisk regarding their application for semaglutide (Wegovy®) for adolescent patients.
- 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.

Further information on the progress of semaglutide (Wegovy®) for adolescent patients through the HSE assessment and approval processes is available via the Pricing and Reimbursement Application tracker available at <https://www.hse.ie/eng/about/who/cpu/> . HSE application ID HSE100034 has been assigned to this application.

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

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