



Feidhmeannacht na Seirbhíse Sláinte, Seirbhís Aisíocaíochta Cúraim Phríomhúil
Bealach amach 5, M50, An Bóthar Thuaidh, Fionnghlas
Baile Átha Cliath 11, D11 XKF3
Fón: (01) 864 7100 Facs: (01) 834 3589

Health Service Executive, Primary Care Reimbursement Service
Exit 5, M50, North Road, Finglas,
Dublin 11, D11 XKF3
Tel: (01) 864 7100 Fax: (01) 834 3589

David Cullinane, T.D.
Dáil Éireann,
Leinster House,
Kildare Street,
Dublin 2.

2nd October 2024

PQ: 37878/24:

To ask the Minister for Health if semaglutide is licenced and approved for use for insulin resistance, weight management or any other purpose in the State; if it is approved or under consideration for reimbursement in any context other than type 2 diabetes; and if he will make a statement on the matter. -David Cullinane

Dear Deputy Cullinane,

The Health Service Executive has been requested to reply directly to you in the context of the above Parliamentary Question (Reference 37878/24), which you submitted to the Minister for Health for response.

Medicines are added to the formal Reimbursement List following detailed assessments which include assessment of the clinical evidence, the economic evidence and the budget impact of a decision to reimburse specific indications of a medicine. The Primary Care Reimbursement Service is required to reimburse in line with approved decisions of the HSE and the HSE is required to formally assess each medicines and each specific use of such medicines before reimbursing them.

Ozempic® (semaglutide) is licensed with the Health Products Regulatory Authority (HPRA) in Ireland and indicated as an adjunct to diet and exercise to improve glycaemic control in adults with type 2 diabetes mellitus. Ozempic® was approved by the HSE for addition to the Reimbursement List for the treatment of Diabetes in 2018. Diabetes is one of the Long Term Illness (LTI) conditions for which eligible LTI persons can access their medicines to treat their Diabetes free of charge.

Controls are in place within the Primary Care Reimbursement Service scheme management systems (and are put in place and updated as required) on claiming processes to ensure that only HSE approved indications are reimbursed across a range of medicines. Controls are currently in place for Ozempic® to restrict reimbursement support to the HSE approved indication of Diabetes against a valid prescription.

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

Wegovy® (semaglutide) is indicated as an adjunct to a reduced-calorie diet and increased physical activity for weight management, however the product is not currently available in Ireland.

Wegovy® (semaglutide) is not reimbursable under Community Drug Schemes or any arrangement as it is undergoing formal pricing and reimbursement assessment under the Health (Pricing and Supply of Medical Goods) Act 2013. A full Health Technology Assessment (HTA) is recommended by the National Centre for Pharmacoeconomics (NCPE) to assess the clinical effectiveness and cost effectiveness of Wegovy® compared with the current standard of care, on the basis of the proposed price relative to current available therapies.

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 assessment 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.

The application for Wegovy® (semaglutide) is ongoing. The HSE cannot make any comment on possible outcomes from the ongoing process.

Yours sincerely,

A handwritten signature in black ink, appearing to read 'Suzanne Doyle'.

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