

Feidhmeannacht na Seirbhíse Sláinte, Seirbhís Aisíocaíochta Cúraim Phríomhúil Bealach amach 5, M50, An Bóthar Thuaidh, Fionnghlas Baile Átha Cliath 11, D11 XKF3

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Michael Healy Rae, T.D. Dáil Éireann, Leinster House, Kildare Street, Dublin 2.

21st February 2025

PQ: 4877/25

To ask the Minister for Health whether there are any plans to add Ozempic to the drugs payment scheme for patients who are prediabetes; and if she will make a statement on the matter. -Michael Healy-Rae

Dear Deputy Healy Rae,

The Health Service Executive has been requested to reply directly to you in the context of the above Parliamentary Question (Reference 4877/25), which you submitted to the Minister for Health for response.

The HSE follows statutory processes around the addition of medicines to the reimbursement list/schemes. Under those statutory processes, the HSE is legally required to consider a range of criteria which include unmet need, clinical evidence, economic evidence, budget impact and the resources available when making reimbursement decisions (i.e. add a medicine to the reimbursement list). The reimbursement decisions have to be in line with the relevant legislation, namely the Health (Pricing and Supply of Medical Goods) Act 2013 (the legislation the HSE operates under for pricing and reimbursement of medicines).

In accordance with the legislation, a medicine must have a marketing authorisation (licence) to be included in the formal list of reimbursable items. A pharmaceutical company can apply to the HSE for reimbursement for a specific indication (use) of a specific licensed medicine. Medicines can have more than one licensed (market authorised) indication and each indication represents a separate application.

Semaglutide (Ozempic®) currently has an EU marketing authorisation for the treatment of adults with insufficiently controlled type 2 diabetes mellitus as an adjunct to diet and exercise. Following EU marketing authorisation for this indication (use), the HSE approved the addition of Semaglutide (Ozempic®) to the list of reimbursable items in September 2018.

Ozempic®) currently does not have an EU marketing authorisation for the treatment of pre-diabetes or any condition other than type 2 diabetes mellitus.

Controls are in place within PCRS on claiming processes to ensure that only HSE approved indications are reimbursed across a range of medicines. Controls are currently in place for the Glucagon-like peptide-1 (GLP-1) receptor agonists to restrict reimbursement support to the HSE approved indication of Diabetes. This includes Victoza® (liraglutide), Ozempic® (semaglutide) and Trulicity® (Dulaglutide).

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. Patients diagnosed with Diabetes Mellitus are entitled to be registered under the LTI Scheme.

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