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Brian Stanley, T.D.
Dáil Éireann,
Leinster House,
Kildare Street,
Dublin 2.

30th May 2025

PQ: 25199/25

To ask the Minister for Health if there are any plans to add Ozempic and Saxenda to the list of medications available under the drugs payment scheme for weight loss programmes; and if she will make a statement on the matter. -Brian Stanley

Dear Deputy Stanley,

The Health Service Executive has been requested to reply directly to you in the context of the above Parliamentary Question (Reference 25199/25), 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 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, the HSE approved the addition of Semaglutide (Ozempic®) to the list of reimbursable items in September 2018.

Ozempic® (semaglutide) currently does not have an EU marketing authorisation for the treatment of obesity 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.

Liraglutide (Saxenda®) 6 mg/ml solution for injection in pre-filled pen is the only product currently approved under Community Drug Schemes (GMS/DPS) for weight management with a managed access system in place as outlined in Circular 002/23 (attached).

In line with the HSE reimbursement approval above, the HSE Medicines Management Programme (MMP) developed a Managed Access Protocol (MAP for liraglutide (Saxenda®) as an adjunct to a reduced-calorie diet and increased physical activity for weight management in adult patients, with an initial BMI of ≥ 35 kg/m² with prediabetes and high-risk for cardiovascular disease.

This MAP outlines the criteria that must be satisfied in order for a patient to be recommended for reimbursement of liraglutide (Saxenda®); further information is available on the MMP website <https://www.hse.ie/eng/about/who/cspd/ncps/medicines-management/managed-access-protocols/liraglutide-saxenda-/liraglutide-saxenda.html>.

As outlined in this MAP, and in line with the reimbursement recommendation, reimbursement is supported for the following subgroup of the licensed population:

- Age 18 - 74 years
- BMI ≥ 35 kg/m²

Confirmation of:

- Participation in non-pharmacological interventions which includes a reduced-calorie diet and increased physical activity e.g. HSE Diabetes Prevention Programme.
- Diagnosis of prediabetes - fasting plasma glucose level between 5.5 - 6.9 mmol/L and Haemoglobin A1c (HbA1c) level between 42 - 47 mmol/mol.
- High-risk for cardiovascular disease – either a total fasting cholesterol level > 5 mmol/L, or mean systolic blood pressure > 140 mmHg

Clinicians are required to submit an application for reimbursement support of liraglutide (Saxenda®) for their patients through an online application system.

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