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Jennifer Murnane O'Connor, T.D.
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7th June 2023

PQ: 25689/23

To ask the Minister for Health the considerations his Department is giving to the inclusion of the drugs saxenda and ozempic, both now recognised as valuable medications in the treatment of obesity, to the drugs payment scheme for non-diabetic patients; if there are plans to widen the prescription of saxenda and ozempic to medical card holders with a BMI of greater than 35 as a preventative medicine; and if he will make a statement on the matter. -Jennifer Murnane O'Connor

Dear Deputy O'Connor,

The Health Service Executive has been requested to reply directly to you in the context of the above Parliamentary Question (Reference 25689/23), 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® (semalgutide) 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. PCRS wrote to GPs last year to state that reimbursement of Ozempic® is only intended in relation to treatment of Diabetes.

Communication was issued to community pharmacy contractors through Circular in 2020 regarding the approved reimbursement indication https://www.hse.ie/eng/staff/pcrs/circulars/pharmacy/pharmacy-circular-022-20-semaglutide-ozempic%C2%AE-.pdf.

Novo Nordisk, the marketing authorisation holder for Ozempic®, has notified the HPRA of intermittent supply issues with Ozempic® products, due to a global increased demand. The company anticipates that intermittent supply will continue into 2023.

Novo Nordisk has informed the HPRA that it has implemented monthly allocations to help ensure continuity of supply and equitable distribution of Ozempic® stock to Irish patients. The company has issued letters to relevant stakeholders, including healthcare professionals to ensure they are aware of this supply issue and how it is being managed https://www.hpra.ie/docs/default-source/Shortages-Docs/ozempic-letter-for-hpra-website.pdf?sfvrsn=2.

Furthermore, the independent regulators the Pharmaceutical Society of Ireland (PSI) and Medical Council have communicated advice to pharmacists and doctors recently (19th May 2023) which is intended to conserve supplies of the product Ozempic for diabetic patients.

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. The HSE expects that as and when the applicant company, Novo Nordisk decides to launch Wegovy® (semaglutide) in Ireland it will progress an application for pricing and reimbursement under Community Drug Schemes.

To enable same the HSE has commissioned a Health Technology Assessment (HTA) for this medicine which will be efficiently assessed when a dossier is submitted by Novo Nordisk. Novo Nordisk have not submitted a dossier to date. Specific queries in relation to plans to market this medicine in Ireland should be directed to Novo Nordisk.

Liraglutide (Saxenda®) 6 mg/ml solution for injection in pre-filled pen is available for reimbursement under the Community Drug Schemes (specifically the Drugs Payment and General Medical Services Schemes) since 1st January 2023.

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.

Applications are reviewed by the MMP on a case-by-case basis, and a reimbursement recommendation is communicated back to the clinician or further information may be requested if required.

The company Novo Nordisk have not submitted a reimbursement application for any other group of the licensed population to the HSE.

Yours sincerely,

Suzanne Doyle
Primary Care Eligibility & Reimbursement Service