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3rd January 2023

Circular 003/23

**RE: Reimbursement of Saxenda® (Liraglutide) 6mg/ml pre-filled pen**

Dear Doctor,

The HSE has approved reimbursement for Liraglutide (Saxenda®) 6 mg/ml solution for injection in pre-filled pen under Community Drug Schemes (GMS/DPS) from 1st January 2023. This product is approved for reimbursement on the basis of managed access. Conditional reimbursement is for a defined subgroup of the licensed population only:

***"Adult patients, as an adjunct to a reduced-calorie diet and increased physical activity for weight management, with an initial body mass index of ≥ 35 kg/m2 with prediabetes and high-risk of cardiovascular disease".***

Due to the potential budget impact associated with this medicine, PCRS has introduced a reimbursement application system to ensure appropriate patients have access to this treatment.

Applications can be made through the Special Drug Request portal under 'Claiming' on the PCRS Doctor Application Suite.

Please see attached letter and supporting information from Prof. Michael Barry, Clinical Lead of the HSE Medicines Management Programme (MMP) outlining further details in relation to reimbursement of Saxenda®.

It is important to note that Victoza® (liraglutide) is not approved for reimbursement for weight management. Prescriptions for Victoza® at doses in excess of 1.8 mg are outside the licensed indication. The maximum quantity allowed under GMS and LTI is one box of Victoza® per month (or a maximum of three pens) for the treatment of adult, adolescents and children aged 10 years and above with Type II Diabetes only.

Yours faithfully,

Shaun Flanagan
Primary Care Eligibility & Reimbursement

**Re: Reimbursement of liraglutide (Saxenda®) 6 mg/ml solution for injection in pre-filled pen**

3rd January 2023

Dear Colleagues,

Liraglutide (Saxenda®) 6 mg/ml solution for injection in pre-filled pen is available for reimbursement under the Community Drug Schemes (CDS), specifically the Drugs Payment (DP) and General Medical Services (GMS) schemes from 1st January 2023. Reimbursement of liraglutide (Saxenda®) is conditional on a managed access protocol (MAP) being in place through the HSE-Medicines Management Programme (MMP) for a defined subgroup of the licensed population, which is:

"***Adult patients, as an adjunct to a reduced-calorie diet and increased physical activity for weight management, with an initial body mass index of ≥ 35 kg/m² with prediabetes and high-risk of cardiovascular disease. Treatment should be discontinued for patients who have not lost ≥ 5 % of their initial body weight after 12 weeks of treatment at the 3.0 mg/day dose".***

GPs and hospital prescribers, once user-registered with the Primary Care Reimbursement Service (PCRS), will be authorised to make an application on an individual patient basis, through the special drug request (SDR) section on the 'GP Application Suite' or under 'Services for Hospitals' on the PCRS website (www.PCRS.ie). The application for reimbursement support should be made by the prescriber responsible for the initiation of treatment.

The MAP for liraglutide (Saxenda®) includes two phases of reimbursement approval. Phase 1 is to ascertain if a patient meets the criteria for initial reimbursement support and approval for this phase is for a duration of six months. For continued reimbursement support after this time, a second reimbursement application is required to demonstrate the patient's response to treatment after 12 weeks of liraglutide (Saxenda®) at the 3 mg/day dose. Once a patient is approved for phase 2 reimbursement support, the total duration of approval is two years from the date of the initial phase 1 application.

Applications submitted for phase 1 will be reviewed by the MMP before a reimbursement recommendation is made. This recommendation will be communicated to the prescriber through the online reimbursement application system. The outcome of phase 2 applications will be automated based on the information provided and the reimbursement recommendation will be immediately visible to the prescriber.

The National Clinical Programme for Obesity has identified a number of resources and local initiatives that are available to prescribers to support adult patients with health behaviours relating to overweight and obesity. For healthcare professionals, 'Making Every Contact Count' (MECC) eLearning course is available on HSELand and includes the module *'Talking about Overweight and Obesity'*. HSE Patient Support Programmes that may be available in your area include the *'Diabetes Prevention Programme'* and *'Best Health Weight Management Programme'.* Further information on these programmes can be sought through your local HSE Community Nutrition and Dietetics Service or HSE Chronic Disease Management Hub. In addition, the HSE 'Talking about weight: A guide to developing healthy habits' booklet provides useful guidance and information to people living with overweight and obesity and is available to order from www.healthpromotion.ie.

Full details of the MAP for liraglutide (Saxenda®) and the additional resources available can be accessed on the MMP website (www.hse.ie/yourmedicines). A copy of the reimbursement information is enclosed for your information.

My thanks for your ongoing support in promoting safe, effective and cost-effective prescribing.

With best wishes,

Michael Barry.

Professor Michael Barry
**National Clinical Lead, Medicines Management Programme.** www.hse.ie/yourmedicines

# Reimbursement Information for Prescribers - Liraglutide (Saxenda®) 6 mg/ml solution for injection

- Liraglutide (Saxenda®) 6 mg/ml solution for injection in pre-filled pen is available for reimbursement under the Community Drug Schemes (CDS), specifically the General Medical Services (GMS) and Drugs Payment (DP) schemes from 1st January 2023.
- Reimbursement is approved for a subgroup of the licensed indication, defined as:
  - **Adult patients, as an adjunct to a reduced-calorie diet and increased physical activity for weight management, with an initial body mass index (BMI) of ≥ 35 kg/m² with prediabetes and high-risk of cardiovascular disease (CVD).**
  - **Treatment should be discontinued for patients who have not lost ≥ 5% of their initial body weight after 12 weeks of treatment on the 3.0 mg/day dose.**
- Starting dose for Saxenda® is 0.6 mg daily by s/c injection. The dose should be increased in increments of 0.6 mg with at least one-week intervals to a maintenance dose of 3.0 mg/daily.

- A Managed Access Protocol (MAP) is in place through the Health Service Executive (HSE) - Medicines Management Programme (MMP) for the defined subgroup outlined above.
- Prescribers once user-registered with the Primary Care Reimbursement Service (PCRS) are required to apply for reimbursement approval on an individual patient basis through the PCRS online application system (www.PCRS.ie). This can be accessed for GPs via the ***'GP Application Suite'*** and for hospital prescribers via ***'Services for Hospitals'.***
- The MAP for Saxenda® 6 mg/ml solution for injection is available on the MMP website and can be accessed at www.hse.ie/yourmedicines.
- Reimbursement of Saxenda® consists of two phases of reimbursement approval:
  - **Phase 1 (Initiation Phase):** Assessment of criteria for initial reimbursement support
  - **Phase 2 (Continuation Phase):** Demonstration of response to Phase 1 of treatment for continued reimbursement support

## Phase 1: Initiation Phase

**Duration of reimbursement approval:** 6 months (24 weeks)
**Requirements for initial reimbursement approval:**

- 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 HbA1c level between 42 - 47 mmol/mol
  - high risk of CVD - total fasting cholesterol level > 5 mmol/L, or mean systolic blood pressure (BP) > 140 mmHg, despite pharmacological treatment
- Each application in Phase 1: Initiation Phase will be reviewed by the MMP

## Phase 2: Continuation Phase

**Duration of reimbursement approval:** 18 months (72 weeks)
**Requirements for continued reimbursement approval:**

- Confirmation of:
  - continued participation in non-pharmacological interventions which includes a reduced-calorie diet and increased physical activity e.g. HSE Diabetes Prevention Programme*
  - updated weight (kg) after 12 weeks of treatment with Saxenda® at a dose of 3 mg daily
- The system will automatically determine the percentage (%) weight change based on the information submitted in the Phase 1: Initiation Phase
- Reimbursement status for Phase 2: Continuation Phase will be immediately visible to the prescriber

- ✓ A new online application will be required if continued approval beyond the total duration of Phase 1 and Phase 2 reimbursement support is sought
- ✓ Reimbursement of liraglutide is supported for a maximum of 13 Saxenda® 6 mg/ml solution for injection in pre-filled pen 5 x 3ml, per year
- ✓ Refer to the Summary of Product Characteristics (SmPC) for full licensing and prescribing information

*** HSE Diabetes Prevention Programme and Best Health Weight Management Programme may be available in your area; for further information, contact your local HSE Community Nutrition and Dietetics Service or HSE Chronic Disease Management Hub.**

**Abbreviations:** **BMI:** Body Mass Index; **BP**: Blood pressure; **CDS**: Community Drug Schemes; **CVD**: Cardiovascular disease; **DP**: Drugs Payment; **GMS**: General Medical Services; **HSE:** Health Service Executive; **MAP**: Managed Access Protocol; **MMP**: Medicines Management Programme; **PCRS**: Primary Care Reimbursement Service; **SmPC**: Summary of Product Characteristics