

# 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 1<sup>st</sup> January 2023.
- Reimbursement is approved for a subgroup of the licensed indication, defined as:
  - **As an adjunct to a reduced-calorie diet and increased physical activity for weight management in adult patients, with an initial body mass index (BMI) of  $\geq 35$  kg/m<sup>2</sup> with prediabetes and high-risk of cardiovascular disease (CVD).**
  - **Treatment should be discontinued for patients who have not lost  $\geq 5\%$  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](http://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/mmp](http://www.hse.ie/mmp).
- 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  $\geq 35$  kg/m<sup>2</sup>
- 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, 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 (Details of current pharmacological treatment(s) are also required and will be taken into consideration when reviewing the application)
- 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 packs of 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