



3rd January 2023

Circular 002/23

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

Dear Pharmacist,

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.

Approval can be confirmed through the ‘Secure Scheme Checker’ on the Pharmacy Suite under ‘Patient Specific Arrangements’. Pharmacies can dispense and claim for Saxenda® electronically using the product GMS code (37709), submitting in the normal manner with monthly claims. Claims submitted for patients who are not approved will not be paid.

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 adults, adolescents and children aged 10 years and above with Type II Diabetes only. The facility is available to pharmacies for 13 dispensing’s in a rolling 12 months to accommodate the shortfall.

Yours faithfully,

Shaun Flanagan
Primary Care Eligibility & Reimbursement

Re: Reimbursement of liraglutide (Saxenda®) 6 mg/ml solution for injection in pre-filled pen3rd 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,



Professor Michael Barry

National Clinical Lead, Medicines Management Programme. www.hse.ie/yourmedicines

Reimbursement Information for Pharmacists - Liraglutide 6 mg/ml solution for injection: Victoza® and Saxenda®

- ✓ Two preparations of liraglutide 6 mg/ml solution for injection are reimbursed under the Community Drug Schemes (CDS) [see Table 1 below] - Victoza® and Saxenda®.
- ✓ Important differences exist between both preparations- see Table 1 and Table 2 below. Refer to the individual SmPCs for full prescribing information.

Table 1: Product information for liraglutide 6 mg/ml solution for injection (Victoza® and Saxenda®)

Medicinal Product	Victoza®	Saxenda®
Reimbursed indication	Adults, Adolescents and Children aged 10 years & above with insufficiently controlled type 2 diabetes mellitus as an adjunct to diet and exercise: <ul style="list-style-type: none"> • as monotherapy when metformin is considered inappropriate due to intolerance or contraindications • in addition to other medicinal products for the treatment of diabetes. 	A subgroup of the full licensed indication is approved for reimbursement: <ul style="list-style-type: none"> • Adult patients, as an adjunct to a reduced-calorie diet and increased physical activity for weight management, with an initial body mass index of $\geq 35 \text{ kg/m}^2$ with prediabetes and high-risk of cardiovascular disease. Treatment should be discontinued for patients who have not lost $\geq 5\%$ of their initial body weight after 12 weeks of treatment at the 3.0 mg/day dose. <ul style="list-style-type: none"> • See SmPC for full prescribing information.
Presentation	2 and 3 pack	5 pack
Dose	Starting dose is 0.6 mg daily. After at least one week the dose should be increased to 1.2 mg. The dose can be further increased after at least one week to a maximum of 1.8 mg daily.	Starting dose is 0.6 mg daily. This dose should be increased in increments of 0.6 mg with at least one-week intervals to a maximum dose of 3.0 mg daily.
CDS	GMS and LTI schemes only.	GMS and DP schemes only.
Reimbursement application system (RAS)	No	Yes- See Medicines Management Programme (MMP) Managed Access Protocol (MAP) which can be accessed at www.hse.ie/yourmedicines . Total duration of reimbursement support is 2 years from the date of the Phase 1 application.
Quantity restrictions	Yes (as per maximum approved dose)	Yes (as per maximum approved dose)

CDS= Community Drug Schemes; DP= Drugs Payment; GMS= General Medical Services; LTI= Long Term Illness; MAP= Managed Access Protocol; MMP= Medicines Management Programme; RAS= Reimbursement Application System; SmPC= Summary of Product Characteristics

Table 2: Liraglutide 6 mg/ml (Victoza® and Saxenda®) solution for injection and appropriate monthly quantities to be dispensed for reimbursement under the CDS

Preparation	Pack size	Total daily dose	GMS code	Price*	Monthly dispensed quantity
Victoza® 6 mg/ml solution for injection in pre-filled pen	2 x 3 ml	1.2 mg	47980	€ 94.01	One box containing two pens per month should be dispensed for patients prescribed 1.2 mg daily.
	3 x 3 ml	1.8 mg	47981	€ 147.10	One box containing three pens per month should be dispensed for patients prescribed 1.8 mg daily.
Saxenda® 6 mg/ml solution for injection in pre-filled pen	5 x 3 ml	3.0 mg	37709	€ 186.98	One box containing five pens per month should be dispensed for patients prescribed 3.0 mg daily , with up to 13 packs supported annually for reimbursement.

*PCRS reimbursement price as of 03/01/2023; CDS= Community Drug Schemes.