Feidhmeannacht na Seirbhíse Sláinte, Seirbhís Aisíocaíochta Cúraim Phríomhúil
Bealach amach 5, M50, An Bóthar Thuaidh, Fionnghlas
Baile Átha Cliath 11, D11 XKF3
Fón: (01) 864 7100 Facs: (01) 834 3589

Health Service Executive, Primary Care Reimbursement Service
Exit 5, M50, North Road, Finglas, Dublin 11, D11 XKF3
Tel: (01) 864 7100 Fax: (01) 834 3589

25th May 2023

Circular 021/23

RE: Saxenda® (Liraglutide) 6 mg/ml Phase 2 Continuation Application

Dear Doctor,

Please find attached communication issued from Prof Michael Barry, National Clinical Lead, HSE Medicines Management Programme in relation to Phase 2 managed access applications for Saxenda® (liraglutide) 6 mg/ml solution for injection.

Full details of the Managed Access Protocol for Saxenda® and the additional resources available can be accessed on the MMP website (www.hse.ie/mmp).

Yours faithfully,

Shaun Flanagan
Assistant National Director
Primary Care Reimbursement Service

Re: Liraglutide (Saxenda®) 6 mg/ml Phase 2 Continuation Application

25th May 2023

Dear Colleagues,

As you are aware, liraglutide (Saxenda®) 6 mg/ml solution for injection in pre-filled pen became available for reimbursement under the Community Drug Schemes (CDS) on 1st January 2023 (Circular 003/23). The 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".***

I would like to remind prescribers that 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. The end date of this approval is visible to prescribers on the online application system.

For continued reimbursement support, a phase 2 reimbursement application is required to be submitted, to demonstrate the patient's response **after 12 weeks of treatment with liraglutide (Saxenda®) at a dose of 3 mg/day**. Please note, the patient's **updated weight in kilograms (kgs) and the date this measurement was taken** must be provided, in addition to confirming if the patient continues to participate in non-pharmacological interventions.

The system will automatically determine the percentage weight change, from the initial weight provided (phase 1 application) to the current weight (phase 2 application). A patient who meets the designated criteria for phase 2 is approved for continued reimbursement support for a total duration of two years from the date of the initial phase 1 application. If a patient does not meet the designated phase 2 criteria, or if the prescriber does not submit a phase 2 application, the patient will no longer be deemed eligible for continued reimbursement support after phase 1 (six months). The outcome of a phase 2 continuation application will be immediately visible to the prescriber.

Full details of the MAP for liraglutide (Saxenda®) and the additional resources available can be accessed on the MMP website (www.hse.ie/mmp).

My thanks for your ongoing support in promoting safe, effective and cost-effective prescribing of liraglutide (Saxenda®).

With best wishes,

Michael Barry.

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