Zorginstituut Nederland

> Return address PO Box 320, 1110 AH Diemen

Ministry of Health, Welfare and Sport
PO Box 20350
2500 EJ THE HAGUE

National Health Care Institute
Care
Medicinal Products

Willem Dudokhof 1
1112 ZA Diemen
PO Box 320
1110 AH Diemen
www.zorginstituutnederland.nl
info@zinl.nl

T +31 (0)20 797 85 55

Contact
Ms J.E. de Boer
T +31 (0)6 215 833 54

2022003019

Our reference
2022003019

Date 24 February 2022
Subject Medicine Reimbursement System advice liraglutide (Saxenda®)

Dear Mr Kuipers,

In your letter of 15 September 2021 (reference CIBG-21-02477), your predecessor asked the National Health Care Institute to assess whether liraglutide (Saxenda®) could be placed on List 1A of the Medicine Reimbursement System. The National Health Care Institute has now completed this assessment. The considerations are included in the report attached to this letter.

Saxenda® is a glucagon-like peptide (GLP-1) analogue. It is available as a solution for injection with 6 mg of liraglutide/ml in a 3 ml pre-filled pen (= 18 mg liraglutide). The therapeutic indication is:

In addition to a reduced-calorie diet and increased physical activity for weight management in adults with an initial BMI of:
- ≥ 30 kg/m² (obesity), or
- ≥ 27 kg/m² to <30 kg/m² (overweight) in the presence of at least one weight-related comorbidity, such as dysglycaemia (pre-diabetes or type 2 diabetes mellitus), hypertension, dyslipidaemia or obstructive sleep apnoea.

The initial dose is subcutaneous 0.6 mg 1×/day; increased by increments of 0.6 mg at intervals of at least 1 week to a maintenance dose of 3.0 mg 1×/day; max. 3.0 mg/day. Consider stopping the treatment if an increase to the next dose step is not tolerated for 2 consecutive weeks. Treatment with liraglutide should be discontinued after 12 weeks on the 3.0 mg/day dose if patients have not lost at least 5% of their initial body weight.

Assessment
The marketing authorisation holder has requested reimbursement for a subset within the registered indication:
In combination with a combined lifestyle intervention (CLI), for the treatment of adults with an extremely increased weight-related health risk (BMI ≥35 kg/m2 in combination with a co-morbidity or BMI ≥40 kg/m2) without type 2 diabetes, and who are not (yet) eligible for metabolic surgery.[1]

[1] Metabolic surgery: surgery on the stomach and/or intestines with the aim of a better metabolism, such as

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The National Health Care Institute concludes that Saxenda® for the group of patients as stated in the marketing authorization holder's application complies with the established medical science and medical practice. For this group, Saxenda® in addition to CLI has a therapeutic added value compared to CLI alone. In this subset of patients, a clinically relevant difference was observed in the percentage of patients reaching ≥10% weight reduction with liraglutide compared to placebo.

The active substance liraglutide is already available as a medicinal product under the brand name Victoza®. Victoza®, like Saxenda®, is available in a 3 ml pen containing 6 mg liraglutide/ml (= 18 mg liraglutide). It is registered for the treatment of type 2 diabetes mellitus and is listed in the GVS on List 1A with the other GLP1 analogues in cluster 0A10BXAP V, with further conditions on List 2 for a subset of type 2 diabetes mellitus patients. This is therefore an extension of the List 2 conditions for liraglutide.

Budget impact analysis (BIA)
Treatment with Saxenda® costs approximately €2600 per patient per year in the maintenance phase. Extension of the current List 2 condition for liraglutide (Saxenda®) will be accompanied by additional costs charged to the pharmaceutical budget of approximately €1.2 million in the third year after inclusion in the health care package. There are a number of uncertainties, such as the number of patients participating in the CLI, and thus the number of patients eligible for Saxenda® in secondary care. There may be a catch-up effort, because the COVID-19 pandemic has prevented many CLI group lessons from taking place. In addition, it is uncertain how many patients are referred to secondary care and the average treatment time with Saxenda® is unknown. There is also uncertainty about the number of patients who continue treatment after 16 weeks. In the BIA, we make the assumption that no patient will stop treatment after 16 weeks. It is possible that in practice, more patients stop than we assume in the BIA. Finally, the BIA has not been corrected for type 2 diabetes, which may slightly overestimate the number of patients.

Cost-effectiveness
Since the budget impact is relatively limited, exemption has been granted for the performance of a pharmaco-economic analysis.

Advice
The National Health Care Institute advises you to extend the reimbursement conditions of liraglutide on the basis of the above considerations. The proposed extension (in italics) is accompanied by limited additional costs.

gastric bypass.

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Condition:

1. only for insured persons with type 2 diabetes mellitus and a BMI ≥ 30 kg/m² whose blood glucose values cannot be adequately regulated with the combination of metformin and a sulphonylurea derivative at the maximum tolerable dosages, and who do not use insulin, unless the insured person is already being treated with this medicinal product in combination with insulin on 1 May 2011.
2. as an addition to metformin and basal insulin (NPH insulin/long-acting analogue insulin) in an insured person with diabetes mellitus type 2 and a BMI ≥ 30 kg/m^2 whose blood glucose values are insufficiently regulated after ≥ 3 months of treatment with optimal titrated basal insulin in combination with metformin (whether or not with a sulphonylurea derivative) in a maximum tolerable dosage.
3. *in combination with a combined lifestyle intervention (CLI) recognized by the RIVM, for the treatment of adults with an extremely increased weight-related health risk, without diabetes mellitus type 2 and who are not (yet) eligible for metabolic surgery:*
   - *BMI ≥35 kg/m2 in combination with a co-morbidity (cardiovascular disease, sleep apnoea and/or osteoarthritis) or*
   - *A BMI ≥40 kg/m2*

   Treatment should be discontinued if after 3 months of using the maintenance dosage the initial weight has not decreased by at least 5%.

Yours sincerely,

Sjaak Wijma
Chair of the Executive Board