Zorginstituut Nederland

Semaglutide (Ozempic®) for the treatment of adults with insufficiently controlled type 2 diabetes mellitus as an adjunct to diet and exercise

Summary of recommendations by *Zorginstituut Nederland* (National Health Care Institute, the Netherlands) dated 28 August 2018.

Zorginstituut Nederland carried out an assessment of the medicinal product semaglutide (Ozempic®) and arrived at the following conclusion.

In a letter dated 11 June 2018 (CIBG-18-0645) the Minister of Health, Welfare and Sport (VWS) asked *Zorginstituut Nederland* to carry out a marginal assessment of whether semaglutide (Ozempic®) can be included in the Medicine Reimbursement System (GVS). The *Zorginstituut* has completed its assessment.

Semaglutide belongs to the pharmacotherapeutic group of GLP-1 (glucagon-like peptide 1) receptor agonists. It is available as 1.34 mg/ml semaglutide for injection in a pre-filled pen with 1.5 ml solution.

It is registered for the treatment of adults with insufficiently controlled type 2 diabetes mellitus as an adjunct to diet and exercise
- as monotherapy when metformin is considered inappropriate due to intolerance or contraindications, or
- in addition to other medicinal products for the treatment of diabetes mellitus type 2.

The starting dose is 0.25 mg semaglutide once weekly. After 4 weeks the dose should be increased to 0.5 mg once weekly. After at least 4 weeks with a dose of 0.5 mg once weekly, the dose can be increased to 1 mg once weekly to further improve glycaemic control.

Assessment of interchangeability
Based on the current criteria, semaglutide (Ozempic®) is interchangeable with the other GLP-1 receptor agonists that are jointly included in cluster 0A10BXAP V of the GVS, namely exenatide, liraglutide, lixisenatide and dulaglutide.

The standard dose of semaglutide can be fixed at 0.07 mg daily.

Advice
Based on our marginal assessment, *Zorginstituut Nederland* advised the Minister to include semaglutide (Ozempic®) on list 1A, in cluster 0A10BXAP V, with a standard dose of 0.07 mg a day.

In addition we advised the Minister that the same reimbursement conditions should apply to the inclusion of semaglutide as to the other GLP-1 receptor agonists in cluster 0A10BXAP V:

Condition
a. adults with type 2 diabetes mellitus and a BMI ≥35 kg/m2, whose blood glucose levels cannot be sufficiently controlled by means of the combination of metformin and a sulphonylurea at the maximum doses tolerated and who do not use insulin.

b. in addition to metformin and basal insulin (NPH-insulin/long-acting insulin analogue) in adults with type 2 diabetes mellitus and a BMI ≥ 30 kg/m2

whose blood glucose levels are insufficiently controlled after ≥ 3 months' treatment with optimally titrated basal insulin in combination with metformin (with or without a sulphonylurea) at the maximum dose tolerated.

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The original text of this excerpt from advice of Zorginstituut Nederland was in Dutch. Although great care was taken in translating the text from Dutch to English, the translation may nevertheless have resulted in discrepancies. Rights may only be derived on the basis of the Dutch version of Zorginstituut Nederland's advice.
Furthermore, Zorginstituut Nederland points out that only the summary of this report was translated. A proper understanding of all relevant considerations and facts would require familiarity with the Dutch version of this report, including all appendices.