



> Return address PO Box 320, 1110 AH Diemen

To the Minister of Medical Care and Sports
PO Box 20350
2500 EJ The Hague

2023024993

Date 14 August 2023
Re: GVS assessment tirzepatide (Mounjaro®)

National Health Care Institute

Care
Medicinal Products

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Our reference

2023024993

Dear Mr Kuipers,

In your letter of 30 May 2023 (CIBG-23-05536), you requested the National Health Care Institute to assess, using a marginal assessment, the reimbursement application of the medicinal product tirzepatide (Mounjaro®) for inclusion in the GVS. The National Health Care Institute has now completed the substantive assessment. The considerations are included in the GVS report attached to this letter.

Tirzepatide is a long acting dual glucose-dependent insulinotropic polypeptide (GIP) and glucagon-like peptide-1 (GLP1) receptor agonist. It is available as a solution for injection in a pre-filled pen. Each pre-filled pen contains 2.5 mg, 5 mg, 7.5 mg, 10 mg, 12.5 mg or 15 mg tirzepatide in a 0.5 ml solution.

The medicinal product is indicated for the treatment of adults with insufficiently controlled type 2 diabetes mellitus as an adjunct to diet and exercise

- as a monotherapy when metformin is considered inappropriate due to intolerance or contraindications
- as an addition to other medicinal products for the treatment of diabetes.

The starting dose of tirzepatide is 2.5 mg once weekly. After 4 weeks, the dose should be increased to 5 mg once weekly. If needed, dose increases can be made in 2.5 mg increments after a minimum of 4 weeks on the current dose. The recommended maintenance doses are 5, 10 and 15 mg. The maximum dosage is 15 weekly.

Assessment of interchangeability

On the basis of the applicable criteria, tirzepatide (Mounjaro®) is interchangeable with the other medicinal products in the GVS cluster 0A10BXAP V, namely liraglutide, lixisenatide, dulaglutide and semaglutide.

The standard dose for tirzepatide can be set at 0.71 mg per day.

Advice

Based on the marginal test we have performed, we recommend that you include tirzepatide (Mounjaro®) in List 1A in the cluster 0A10BXAP V with a standard dose of 0.71 mg per day.

In addition, we recommend that you place tirzepatide on List 2, with the same conditions as the other medicinal products in the cluster.

Condition

Only for insured persons aged 18 years or older with:

- a. type 2 diabetes mellitus and a BMI ≥ 30 kg/m² whose blood glucose levels cannot be sufficiently controlled with the combination of metformin and a sulphonylurea derivative at the maximum doses tolerated, and who do not use insulin,*

- b. as an addition to metformin and basal insulin (NPH insulin/long-acting analogue insulin) for an insured person with diabetes mellitus type 2 and a BMI ≥ 30 kg/m² whose blood glucose values are insufficiently controlled after ≥ 3 months of treatment with optimal titrated basal insulin in combination with metformin (with or without a sulphonylurea derivative) at the maximum dose tolerated.*

Yours sincerely,

Sjaak Wijma
Chairperson of the Executive Board

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Institute**
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