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To the Minister of Health, Welfare and Sport
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2026005831

National Health Care Institute
Research, Development and Medicinal Products
Medicinal Products Team

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Our reference
2026005831

Date 19 March 2026
Re: GVS advice on expansion of additional conditions for tirzepatide (Mounjaro®) for patients with diabetes and a very high risk of cardiovascular disease

Dear Ms Hermans,

In this letter, the National Health Care Institute advises you on the extension of the List 2 conditions for the use of tirzepatide in patients with type 2 diabetes mellitus and a very high risk of cardiovascular disease.
This advice was prompted by your request in the letter of 9 March 2026 (CIBG-26-09492).

Condition
Type 2 diabetes mellitus is a disease in which there is too much glucose in the blood. This occurs because the body has become less sensitive to insulin or because the body does not produce enough insulin. Symptoms of type 2 diabetes mellitus include thirst, recurrent bladder infections, blurred vision and fatigue. In the long term, damage to the eyes, kidneys and nerves can occur, and cardiovascular diseases may also develop. As a result, patients may eventually die at an early age.

Registered indications:
Tirzepatide is indicated for the treatment of adults with inadequately controlled type 2 diabetes mellitus, as an adjunct to diet and exercise
• as monotherapy when metformin is considered unsuitable due to intolerance or contraindications
• in adjunct to other medicinal products for the treatment of diabetes.

The medicinal product is available as a subcutaneous injection in a pre-filled pen and as a solution in a vial. The National Health Care Institute is currently also assessing tirzepatide for use in the treatment of obesity.

The current reimbursement conditions for tirzepatide are as follows:
exclusively for an insured person aged 18 years and older:

1. *With type 2 diabetes mellitus and a BMI ≥ 30kg/m^2, whose blood glucose levels are not adequately controlled with the combination of metformin and a sulphonylurea derivative at the maximum tolerated doses, and who is do not use insulin, or*
2. *as an adjunct to metformin and basal insulin (NHP insulin/long-acting*

insulin analogue) in an insured person with type 2 diabetes mellitus and a BMI ≥ 30 kg/m^2 whose blood glucose levels are not adequately controlled after ≥ 3 months of treatment with optimally titrated basal insulin in combination with metformin (with or without a sulphonylurea derivative) at a maximum tolerated dose.

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Claim by the marketing authorisation holder (MAH)
Tirzepatide (Mounjaro®) has a similar value to dulaglutide, exenatide, liraglutide and semaglutide in the treatment of patients with type 2 diabetes mellitus and a very high risk of cardiovascular disease.

Tirzepatide is already included in List 1A in the 0A10BXAP V cluster. This cluster also includes dulaglutide, exenatide, liraglutide and semaglutide. The marketing authorisation holder requests the expansion of the additional conditions for tirzepatide for patients with type 2 diabetes mellitus and a very high risk of cardiovascular disease.

Advice
The national Health Care Institute advises you to expand the additional conditions for tirzepatide, in line with the conditions for dulaglutide, exenatide, liraglutide and semaglutide, on List 2 of the GVS as follows:

3. *As an adjunct to an SGLT2 inhibitor and metformin, or where there is a contraindication for an SGLT2 inhibitor, added to standard treatment in an insured person with type 2 diabetes mellitus and a very high risk of cardiovascular disease (in accordance with the NHG guideline for type 2 diabetes mellitus):*
    1. *with previously diagnosed cardiovascular disease, and/or*
    2. *chronic kidney damage.*

We have explained below how we reached this advice.

Substantive assessment
Therapeutic value
In the randomised SURPASS-CVOT study, tirzepatide was directly compared to dulaglutide in patients with atherosclerotic cardiovascular disease. This shows that the effectiveness of both medicinal products in preventing death from cardiovascular disease, non-fatal myocardial infarction, or non-fatal stroke is similar. The adverse reaction profiles are also similar.

In a previous group assessment, the National Health Care Institute has already established that dulaglutide, exenatide, liraglutide and semaglutide all have added value compared to standard treatment in patients with type 2 diabetes mellitus and a very high risk of cardiovascular disease. The National Health Care Institute concludes that tirzepatide for the aforementioned indication meets the established medical science and medical practice and, as such, has an equivalent value to dulaglutide, exenatide, liraglutide and semaglutide.

Budget impact analysis
Due to the equal value and the fact that tirzepatide is already clustered on List 1A with dulaglutide, exenatide, liraglutide and semaglutide, the adjustment of the additional condition should, in principle, be budget-neutral.

Should you need any further information, please do not hesitate to contact us.

Yours sincerely,

M.J. Janssen
Chairperson of the Executive Board

Enclosed:
-Pharmacotherapeutic report

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