



> Return address PO Box 320, 1110 AH Diemen

Minister of Medical Care and Sports
PO Box 20350
2500 EJ THE HAGUE

2021021817

Date 22 June 2021
Subject GVS report SGLT-2 inhibitors

National Health Care Institute

Care I
Oncology
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

Our reference

2021021817

Dear Ms van Ark,

In your letter of 16 March 2021 (reference CIBG-21-01601), you asked the National Health Care Institute to assess whether the further conditions of SGLT-2 inhibitors canagliflozin (Invokana®), dapagliflozin (Forxiga®), empagliflozin (Jardiance®), ertugliflozin (Steglatro®), could be extended. The National Health Care Institute has now completed this assessment. The considerations are included in the report attached to this letter.

Background

The Round Table for Diabetes Care, a joint venture initiated by the Dutch Diabetes Federation (NDF) and the National Health Care Institute, proposed that an extension of the List 2 criteria be pursued for these medicinal products, given the benefits in patients with diabetes mellitus type 2 and a very high risk of cardiovascular disease. The extension requested, in addition to the current List 2 conditions, is for patients with diabetes mellitus type 2 who have a very high risk of cardiovascular disease, as an addition to the standard treatment. In support of this request, the physicians associations of general practitioners and internists (NHG and NIV) have issued an advice on the use of SGLT-2 inhibitors in the said patient group.¹

The present List 2 conditions are:

canagliflozin, dapagliflozin

Condition:

only for an insured person with type 2 diabetes mellitus who cannot be treated with the combination of metformin and sulfonylurea derivative, does not use insulin and uses this medicinal product as a dual or triple treatment in combination with metformin and/or sulfonylurea derivative.

¹ Dutch College of General Practitioners – Dutch Internists Association. Concept guideline Pharmacotherapy for high-risk patients with Diabetes Mellitus type 2. 2021

empagliflozin

Condition:

only for an insured person with type 2 diabetes mellitus who cannot be treated with the combination of metformin and sulfonylurea derivative, does not use insulin and uses this medicinal product as a dual combination with metformin or triple treatment in combination with metformin and/or sulfonylurea derivative.

ertugliflozin

Condition:

only for an insured person with type 2 diabetes mellitus who cannot be treated with the combination of metformin and sulfonylurea derivative, does not use insulin and uses this medicinal product as a dual treatment in combination with metformin.

Assessment of therapeutic value

The National Health Care Institute has reached the final conclusion that the SGLT-2 inhibitors canagliflozin, dapagliflozin and empagliflozin in the treatment of patients with diabetes mellitus type 2 (DM2) and a very high risk of cardiovascular disease have a therapeutic added value compared to placebo. They are thus part of the established medical science and medical practice. Ertugliflozin does not meet the established medical science and medical practice.

Budget impact analysis

Taking into account the assumptions regarding patient numbers, market penetration and patient compliance, the extension of the List 2 conditions for the SGLT-2 inhibitors canagliflozin, dapagliflozin and empagliflozin for the application in patients with DM2 and a very high risk of cardiovascular disease are associated with additional costs to the pharmaceutical budget ranging from €3 million up to €11.9 million, depending on assumptions regarding market penetration.

Cost-effectiveness

Although the cost-effectiveness analysis is not sufficiently transparent on a number of points, the National Health Care Institute concludes that the cost-effectiveness analysis is of sufficient methodological quality. The marketing authorisation holders report an ICER of €3,304 per QALY. The National Health Care Institute concludes that the SGLT-2 inhibitors at the reference value of €50,000 per QALY are cost-effective compared to the standard treatment.

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Advice

On the basis of the above, we advise you to extend the List 2 conditions of the SGLT-2 inhibitors canagliflozin (Invokana®), dapagliflozin (Forxiga®) and empagliflozin (Jardiance®) with the following condition:

Condition:

For the treatment of adults with diabetes mellitus type 2 with a very high risk of cardiovascular disease:

- Established cardiovascular diseases; and/or
- Chronic kidney damage with
 - eGFR 30-59 ml/min per 1.73m², with moderately increased albuminuria (ACR> 3 mg/mmol/l) or
 - eGFR ≥ 60 ml/min per 1.73m² with severely increased albuminuria (ACR>30 mg/mmol).

Yours sincerely,

Sjaak Wijma
Chair of the Executive Board

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