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Our reference
2021041333

Date 21 October 2021
Subject GVS assessment empagliflozin (Jardiance®)

Dear Mr Blokhuis,

In your letter of 17 August 2021 (reference CIBG-21-2262), you asked the National Health Care Institute to assess whether the further condition of empagliflozin (Jardiance®) 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
Empagliflozin is an oral blood glucose reducing agent that selectively inhibits the sodium/glucose cotransporter 2 (SGLT2) in the renal tubuli. It is currently included on List 1A in the GVS in cluster 0A10BXAO V, along with the other SGLT2 inhibitors canagliflozin, empagliflozin and ertugliflozin. The reimbursement is arranged through a List 2 condition:

1. 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 a sulfonylurea derivative.
2. For the treatment of people 18 years and older with type 2 diabetes mellitus with a very high risk of cardiovascular disease:
    1. With previously proven cardiovascular diseases; and/or
    2. Chronic kidney damage with
    - eGFR 30- -59 ml/min per 1.73m^2 with moderately elevated albuminuria (ACR > 3 mg/mmol) or
    - eGFR ≥ 60 ml/min per 1.73m^2 with severely increased albuminuria (ACR > 30 mg/mmol).

Furthermore, the National Health Care Institute recently (on 21 September) issued an additional advice to you, with the recommendation to extend the above-mentioned List 2 condition under section 2.2 to include:

- eGFR 30-44 ml/min per 1.73m2 without albuminuria

National Health Care Institute
Business Services

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Current request
The current application is related to an extension of the reimbursement condition based on the newly registered indication: for use in adults for the treatment of symptomatic chronic heart failure with reduced injection fraction. The recommended dosage for this indication is 10 mg per day, added to the default background treatment for heart failure.

Assessment of therapeutic value
Empagliflozin complies with the established medical science and medical practice in adults with symptomatic chronic heart failure with reduced ejection fraction. On the basis of the data, the National Health Care Institute concludes that empagliflozin has an equal value with respect to dapagliflozin (Forxiga®).

Budget impact analysis
Taking into account the assumptions surrounding patient numbers, market penetration and patient compliance, the indication extension of empagliflozin (Jardiance®) in adults with symptomatic chronic heart failure with reduced ejection fraction will be accompanied by additional costs charged to the pharmaceutical budget of approximately €0.6 million in the third year after market introduction. This is the base case scenario. Assuming a maximum scenario, where market penetration is doubled, the additional costs will be €1.1 million. These calculations take into account the substitution of dapagliflozin.

Advice
On the basis of the above, we recommend that you extend the reimbursement condition for empagliflozin, as was previously done for dapagliflozin, with the following condition:

Condition:
For adult patients with symptomatic (NYHA II-IV) chronic heart failure with reduced ejection fraction (LVEF<40%)

Yours sincerely,

Sjaak Wijma
Chair of the Executive Board