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Our reference
2021014237

Date 12 May 2021
Subject Extension of further condition for dapagliflozin (Forxiga®)

Dear Ms van Ark,

In your letter of 12 January 2021 (reference CIBG-21-01333), you asked the National Health Care Institute to assess whether the further condition of dapagliflozin (Forxiga®) 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
Dapagliflozin (as propanediol monohydrate) 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:

> 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.

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 in that case is 10 mg per day, added to the default background treatment for heart failure.

Assessment of therapeutic value
The National Health Care Institute has reached the final conclusion that in treating symptomatic chronic heart failure with reduced ejection fraction (LVEF≤40%), dapagliflozin adds therapeutic value to the standard treatment, compared to only standard treatment in patients with NYHA Class II to IV. The conclusion is that dapagliflozin with this indication meets the established medical science and medical practice.

Budget impact analysis
Taking into account the assumptions about patient numbers, market penetration and patient compliance, increasing the reimbursement condition for dapagliflozin (Forxiga®) in symptomatic chronic heart failure with reduced ejection fraction will be accompanied by additional costs charged to the pharmaceutical budget of at least €13.1 million to a maximum of €26.2 million in the third year. This applies to a patient number of at least 24,000 to 49,000.

Cost-effectiveness
The results of the probabilistic sensitivity analysis as reported by the marketing authorisation holder show that the probability of dapagliflozin being cost-effective compared to the placebo at a reference value of €50,000 per QALY is 100%. The average ICER of the 1,000 simulations that the marketing authorisation holder performed was €15,583 per QALY.

Advice
On the basis of the above, we recommend that you extend the reimbursement condition for dapagliflozin with the following condition:

Condition:
In 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

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