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2022008811

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Our reference
2022012771

Date 28 March 2022
Subject Expansion of the further conditions for dapagliflozin (Forxiga®)

Dear Mr Kuipers,

This is a corrected version of the letter previously sent on 23 March 2022 (reference 2022008811) in which the List 2 conditions have been corrected.

In his letter of 8 November 2021 (reference CIBG-21-012768), your predecessor in office asked the National Health Care Institute to assess whether the further conditions for 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 the propanediol monohydrate) is an oral blood glucose reducing agent that selectively inhibits the sodium/glucose cotransporter 2 (SGLT2) in the renal tubuli. It is available as film-coated tablets of 5 and 10 mg. The registered indication to be evaluated is for the treatment of chronic kidney disease in adults .

Forxiga® is registered for the treatment of type 2 diabetes mellitus and is listed in the Medicine Reimbursement System (GVS) on List 1A along with other SGLT2 inhibitors in cluster 0A10BXAO V, with further conditions on List 2. The current application is related to an extension of the reimbursement conditions based on the newly licensed indication. The recommended dosage is 10 mg dapagliflozin per day, added to the standard background treatment for chronic kidney disease.

Assessment of therapeutic value
The National Health Care Institute concludes that dapagliflozin for use in adults for the treatment of chronic kidney disease complies with established medical science and medical practice. Forxiga® has therapeutic added value for these patients compared to the standard treatment alone. Clinically relevant reduced risks of renal function deterioration, renal failure or renal death were observed in these patients. Treatment with dapagliflozin also reduces the risk of cardiovascular mortality and exacerbation of heart failure.

Budget impact analysis (BIA)
Treatment with Forxiga® costs approximately €408.94 per patient per year. Taking into account the assumptions about patient numbers and market penetration, expanding the reimbursement conditions for dapagliflozin (Forxiga®) for chronic kidney disease will be accompanied by additional costs of approximately €32.2 million in year 3.

Cost-effectiveness
Treatment consisting of the standard treatment plus dapagliflozin results in a dominant ICER compared to standard treatment alone. This means that treatment with dapagliflozin gives more quality-adjusted life years (QALYs) at a lower cost than the standard treatment. Sensitivity analyses give the National Health Care Institute sufficient confidence that adding dapagliflozin to the standard treatment will both reduce costs from a social perspective and improve patient outcomes.

The results of the probabilistic sensitivity analysis as reported by the marketing authorisation holder show that the probability of dapagliflozin being cost-effective is 100% at a reference value of €20,000 per QALY gained.

Advice
The National Health Care Institute advises you to extend the reimbursement conditions of dapagliflozin on the basis of the considerations above. The proposed extension (in italics) is accompanied by additional costs.

Condition:
only for insured persons

1. with type 2 diabetes mellitus who cannot be treated with the combination of metformin and a sulfonylurea derivative, who do not use insulin and use this medicinal product as a dual or triple treatment in combination with metformin and/or a sulfonylurea derivative,
2. aged eighteen and older with symptomatic (NYHA II-IV) chronic heart failure with reduced ejection fraction (LVEF <40%),
3. aged eighteen and older with type 2 diabetes mellitus with a very high risk of cardiovascular disease and previously diagnosed cardiovascular disease, or
4. *aged eighteen and older with chronic kidney disease.*

Yours sincerely,

Sjaak Wijma
Chair of the Executive Board

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