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2023002627

National Health Care Institute
Care
Medicinal Products

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Our reference
2023002627

Date 31 January 2023
Subject Extension of further condition for empagliflozin (Jardiance®)

Dear Mr Kuipers,

In your letter of 27 June 2022 (reference CIBG-22-04007), you asked the National Health Care Institute to assess whether the List 2 condition of empagliflozin (Jardiance®) for patients with symptomatic (NYHA II–IV) chronic heart failure can be extended.

The National Health Care Institute has now completed that assessment. The considerations are set out in the attached reports.

Background
Empagliflozin has been included in the Medicine Reimbursement System (GVS) on List 1A in cluster 0A10BXAO V along with canagliflozin, dapagliflozin and ertugliflozin. The reimbursement is arranged through List 2 conditions:

Only for insured persons:
1 with type 2 diabetes mellitus who cannot be treated with the combination of metformin and a sulfonylurea derivative, do not use insulin and use this medicinal product as a dual combination with metformin or triple treatment in combination with metformin and/or a sulphonylurea derivative,
2 ***aged eighteen and older with symptomatic (NYHA II-IV) chronic heart failure with reduced ejection fraction (LVEF <40%),*** *or*
3 For the treatment of people 18 years and older with type 2 diabetes mellitus with a very high risk of cardiovascular disease:
a. with previously proven cardiovascular disease; and/or
b. chronic kidney damage with
- eGFR 30-44 ml/min per 1.73m2 without albuminuria,
- eGFR 30-59 ml/min per 1.73m2 with moderately elevated albuminuria (ACR > 3 mg/mmol) or
- eGFR ≥ 60 ml/min per 1.73m2 with severely increased albuminuria (ACR > 30 mg/mmol).

Current request
The current request relates to the extension of the reimbursement condition for symptomatic (NYHA II-IV) chronic heart failure, and is based on the registration granted by the European Medicines Agency (EMA) in 2022 for the treatment of adults with symptomatic chronic heart failure regardless of the ejection fraction

(LVEF). The now requested extension is therefore specifically related to patients with symptomatic (NYHA II-IV) chronic heart failure and an LVEF >40%. The recommended dosage in that case is 10 mg per day, added to the standard background treatment for heart failure.

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Assessment of therapeutic value
The National Health Care Institute has concluded that empagliflozin added to the standard treatment also has a therapeutic added value compared to the standard treatment alone in patients with symptomatic (NYHA II-IV) chronic heart failure with an LVEF >40%. As such, empagliflozin meets the established medical science and medical practice for this indication.

Budget impact analysis
Taking into account the assumptions about patient numbers, market penetration and compliance, the indication extension of empagliflozin in adults with symptomatic (NYHA II-IV) chronic heart failure with an LVEF >40% is expected to result in 15,913 patients eligible for treatment in the third year. The additional costs at the expense of the pharmaceutical budget in this base case scenario will amount to approximately €7.9 million in the third year. Due to the ever-changing medical insights about appropriate heart failure care, there is a lot of uncertainty in this scenario about the number of patients and market penetration.

Cost-effectiveness
The National Health Care Institute concludes that the pharmaco-economic analysis is of sufficient quality and that it can be used for decision-making. The National Health Care Institute is of the opinion that the ICER of € 8,863, as reported by the marketing authorisation holder, is a slight underestimation of the reality. This is related to the inaccuracy of various aspects of the pharmaco-economic model. However, on the basis of scenario analyses, the National Health Care Institute concludes that the ICER is well below the reference value of €50,000 per QALY, and therefore that empagliflozin for this indication is cost-effective compared to the standard treatment.

Advice
On the above grounds, the National Health Care Institute recommends that you adjust the current List 2 condition (for symptomatic (NYHA II-IV) chronic heart failure with reduced ejection fraction (LVEF < 40%) as follows:

Condition:
For adult patients with symptomatic (NYHA II-IV) chronic heart failure

Yours sincerely,

Sjaak Wijma
Chairperson of the Executive Board