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2022012185

Our reference
2022012185

Date 4 April 2022
Re: GVS advice on finerenon (Kerendia®)

Dear Mr Kuipers,

In your letter of 5 January 2022 (reference CIBG-21-03111), your predecessor asked the National Health Care Institute to assess whether the product finerenon (Kerendia®) can be included in the Medicine Reimbursement System (GVS). The National Health Care Institute has now completed the substantive assessment. The considerations are included in the GVS report attached to this letter, with the pharmaco-therapeutic report and the budget impact analysis.

Kerendia® is indicated for the treatment of patients with chronic kidney disease (CKD) (stage 3 or 4 with albuminuria) in adults with diabetes mellitus type 2 (DM2).

Kerendia® is available as 10 mg and 20 mg film-coated tablets. The recommended starting dose is 10 mg of finerenon once a day in patients with an eGFR of ≥25 ml/min/1.73m^2 and potassium levels of ≤5.0 mmol/L and 20 mg finerenon once a day in patients with an eGFR of ≥60 ml/min/1.73m^2 and potassium levels of ≤5.0 mmol/L. After 4 weeks, the renal function and potassium concentration in the blood serum must be determined. The dosage can be increased to 20 mg once a day if the potassium level is ≤4.8 mmol/L and the kidney function has not deteriorated by more than 30%. With a potassium level between 4.8 and 5.5 mmol/L, the daily dosage of 10 mg can be continued and with a higher potassium level (>5.5 mmol/L), finerenon must be discontinued.

The market authorisation holder is asking for inclusion on List 1B of the Health Insurance Regulation.

Outcome of the substantive assessment
Review of interchangeability
Based on the criteria for interchangeability, finerenon (Kerendia®) is not interchangeable with other medicinal products included in the GVS. Based on this, Kerendia® cannot be placed on List 1A. Next, the National Health Care Institute assessed whether Kerendia® is eligible for inclusion on List 1B and was advised on this matter by the Scientific Advisory Board (WAR).

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Therapeutic value
Reimbursement is requested for the treatment of CKD in adults with DM2 according to the registered indication. Currently, these patients receive lifestyle recommendations and are treated with cardiovascular risk management with statins (possibly in combination with ezetimibe) and antihypertensive medicinal products. Especially in moderately/strongly elevated albuminuria, renin angiotensin-aldosterone system (RAAS) inhibitors (angiotensin-converting enzyme (ACE) inhibitors or angiotensin-receptor blockers (ARBs) are preferred. Sodium-glucose-linked-transporter-2 (SGLT-2) inhibitors are already recommended in patients with very high risk of cardiovascular disease (CVD), including CKD, and DM2.

The National Health Care Institute concludes that finerenon for the treatment of CKD (stage 3 or 4 with albuminuria) in adult patients with DM2 meets the established medical science and medical practice. It has a therapeutic added value compared to standard treatment only, as it gives these patients a clinically relevant lower risk of kidney function deterioration, renal failure or renal death, hospitalisation for heart failure, cardiovascular mortality or non-fatal myocardial infarction or stroke. Finereron also probably creates a clinically relevant reduction of the mortality risk regardless of the cause.

Budget impact analysis (BIA)
Treatment with finerenon costs €730.00 per patient per year. Taking into account the assumptions about the assumed place in the treatment regime, the patient population and the market penetration, the extension of the reimbursement conditions of finerenon for patients with CKD with DM2 is expected to be accompanied by additional costs charged to the pharmaceutical budget of approximately €4.7 to €9.3 million in the third year after inclusion in the basic insured package.

Pharmaco-economic analysis
Based on the estimated budget impact, the product is exempt from pharmaco-economic analysis.

Advice
The National Health Care Institute recommends that finerenon (Kerendia®) be included in List 1B of the GVS, with the following reimbursement condition:
Only for insured persons aged 18 and older with chronic kidney disease with diabetes mellitus type 2.

Yours sincerely,

Sjaak Wijma
Chairperson of the Executive Board