SUMMARY

finerenone

KERENDIA 10 mg and 20 mg

film-coated tablets

Indication extension

Original French opinion adopted by the Transparency Committee on 20 September 2023

The legally binding text is the original French opinion version

Transparency Committee's conclusions

Clinical Benefit

- Chronic kidney disease associated with type 2 diabetes is a disease naturally progressing to serious, potentially life-threatening, complications, with a substantial impact on patient quality of life and the healthcare system at the dialysis or transplant stage.
- This is a medicinal product intended to prevent renal complications.
- The efficacy/adverse effects ratio is low, given demonstration of a benefit only in terms of reduction of hospitalisations for heart failure, but not on the ranked renal composite secondary endpoint, in stage 1 or 2 CKD with albuminuria in patients with type 2 diabetes,
- KERENDIA (finerenone) is a treatment for stage 1 or 2 chronic kidney disease (with albuminuria) associated with type 2 diabetes, only in addition to the optimised standard of care with an angiotensin-converting enzyme inhibitor (ACEi) or angiotensin receptor blocker (ARB). A clinical benefit of its use as monotherapy or in combination with a gliflozin has not been demonstrated.

- **Public health benefit**

Considering:

- the seriousness of the disease, with a natural progression to serious complications, with a significant impact on the patient's quality of life and the healthcare system at the dialysis or transplant stage, and which can be fatal,
- its prevalence and incidence,
- the partially met medical need,

- the partial response provided by KERENDIA (finerenone) to the identified medical need, given:
  - an additional impact demonstrated only on a cardiovascular composite endpoint (related solely to hospitalisation for heart failure), and without a demonstrated impact on renal morbidity and mortality,
  - the absence of conclusive data on a potential impact on quality of life,
- the lack of data on a potential impact on the organisation of care,

KERENDIA (finerenone) is unlikely to have an additional impact on public health.

Considering all these elements, the Committee deems that the clinical benefit of KERENDIA 10 mg and 20 mg (finerenone) film-coated tablets is low in stage 1 or 2 chronic kidney disease (with albuminuria) associated with type 2 diabetes.

The Committee issues a favourable opinion for inclusion of KERENDIA 10 mg and 20 mg (finerenone) film-coated tablets in both the hospital formulary list and the retail formulary list of reimbursed proprietary medicinal products approved for use in stage 1 or 2 chronic kidney disease (with albuminuria) associated with type 2 diabetes and at the MA dosages.

➔ **Recommended reimbursement rate: 15%**

Clinical Added Value

Considering:

- the demonstrated superiority of KERENDIA (finerenone) compared to placebo, in combination with the optimised standard of care with ACEi or ARB on the composite primary endpoint, including cardiovascular death, non-fatal myocardial infarction (MI), non-fatal stroke or hospitalisation for heart failure, with 458 patients in the finerenone group (12.4%) versus 519 patients in the placebo group (14.2%), HR = 0.87; CI95% [0.76; 0.98]; p=0.0264,
- an effect size attributable to the reduction in hospitalisations for heart failure, HR = 0.71; CI95% [0.56; 0.90], p<0.0043,
- the value of this result in a population of diabetes patients with stage 1 or 2 chronic kidney disease and albuminuria, heart failure being one of the risk factors for exacerbation of chronic kidney disease,
- but the absence of any demonstration of a benefit on the first ranked secondary endpoint, which was renal composite endpoint including end-stage renal disease, durable reduction in estimated glomerular filtration rate > 40% compared to baseline or renal death,
- an acceptable comparison versus placebo in view of the concomitant development of KERENDIA (finerenone) in relation to gliflozins,
- the safety profile of KERENDIA (finerenone) marked by a hyperkalaemia risk, which may be increased with concomitant use of medicinal products liable to raise serum potassium levels, e.g. ACEi or ARB, leading to more frequent blood potassium monitoring for some patients, particularly kidney failure patients,
- the lack of robust quality of life results,

the Committee deems that KERENDIA (finerenone) provides no clinical added value (CAV V) in the care pathway for stage 1 or 2 chronic kidney disease (with albuminuria) associated with type 2 diabetes, excluding gliflozins.

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