SUMMARY

empagliflozin

JARDIANCE 10 mg

film-coated tablets

Indication extension

Original French opinion adopted by the Transparency Committee on 31 January 2024

The legally binding text is the original French opinion version

Transparency Committee's conclusions

Clinical Benefit

- Chronic kidney disease is a condition 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 transplantation stage, and which can be fatal.
- This is a preventive medicinal product.
- The efficacy/adverse effects ratio is high in the treatment of adult patients with chronic kidney disease with an estimated glomerular filtration rate (eGFR) between 20 and 45 mL/min/1.73m² or between 45 and 90 mL/min/1.73m² with a urine albumin to creatinine ratio (UACR) of ≥ 200 mg/g, as an adjunct to standard of care therapy.
- JARDIANCE (empagliflozin) is a treatment for adult patients with chronic kidney disease with an estimated glomerular filtration rate (eGFR) between 20 and 45 mL/min/1.73m² or between 45 and 90 mL/min/1.73m² with a urine albumin to creatinine ratio (UACR) of ≥ 200 mg/g, as an adjunct to optimised standard of care therapy with an angiotensin-converting enzyme (ACE) inhibitor or angiotensin receptor blocker (ARB). A clinical benefit of its use as monotherapy 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 medical need partially met by the available alternatives,
- the partial response to the identified need, due to:
  - the demonstrated impact on morbidity (reduction in all-cause hospitalisations), without a demonstrated impact on mortality,

- the absence of robust results on quality of life,
- the lack of data on a potential impact on the organisation of care,

JARDIANCE (empagliflozin) is unlikely to have an additional impact on public health.

Considering all these elements, the Committee deems that the clinical benefit of JARDIANCE (empagliflozin) is:

- **substantial only as an adjunct to standard of care therapy in the treatment of adult patients with chronic kidney disease:**
  - **with an estimated glomerular filtration rate (eGFR) between 20 and 45 mL/min/1.73m² or between 45 and 90 mL/min/1.73m² with a urine albumin to creatinine ratio (UACR) of ≥ 200 mg/g,**
  - **treated with an angiotensin-converting enzyme (ACE) inhibitor or angiotensin receptor blocker (ARB or sartan) at the maximum tolerated dose,**
- **insufficient to justify public funding in view of the available alternatives in the other MA situations.**

The Committee issues the following opinions:

- **a favourable opinion for inclusion of JARDIANCE (empagliflozin) in both the list of covered drugs for outpatients and in the list of covered drugs for inpatients approved for use in the scope retained.**
- **an unfavourable opinion for inclusion of JARDIANCE (empagliflozin) in both the list of covered drugs for outpatients and in the list of covered drugs for inpatients approved for use in the other situations covered by the MA indication.**

➔ **Recommended reimbursement rate for inclusion in the list of covered drugs for outpatients: 65%**

Clinical Added Value

Considering:

- the demonstrated superiority of JARDIANCE (empagliflozin) compared to placebo, in combination with the optimised standard of care therapy with an ACE inhibitor or ARB, in the EMPA-KIDNEY study, on the composite primary endpoint including kidney disease progression to ESKD, or a sustained decrease in eGFR of ≥ 40%, or a sustained decrease in eGFR to <10 mL/min/1.73 m^2, or death from renal causes, or death from cardiovascular causes: 432 (13.1%) patients in the empagliflozin group versus 558 (16.9%) patients in the placebo group, HR=0.72; 95% CI [0.64; 0.82]; p<0.0001),
- an effect size driven by the decrease in eGFR of ≥ 40% (8.9% versus 11.3%),
- a statistically significant difference for only one of the secondary endpoints with management of the alpha risk, i.e. the time to hospitalisation for any cause (HR=0.86; 95% CI [0.78; 0.95]; p = 0.0025), and the lack of any demonstrated statistically significant difference for hospitalisation for heart failure, death from a cardiovascular cause and death from any cause,
- an acceptable comparison versus placebo in view of the concomitant development of JARDIANCE (empagliflozin) in relation to other gliflozins and finerone,
- the safety profile of JARDIANCE (empagliflozin) in this indication extension, which appears to be similar to that observed in the other indications of the MA,
- the lack of robust quality of life results,

the Committee considers that JARDIANCE (empagliflozin) provides a minor clinical added value (CAV IV) in the current care pathway, excluding other gliflozins.