SUMMARY

voclosporin

LUPKYNIS 7.9 mg,

soft capsule

First assessment

Adopted by the Transparency Committee on 5 April 2023

The legally binding text is the original French opinion version

Key points

Unfavourable opinion on reimbursement in the MA indication: "Lupkynis is indicated in combination with mycophenolate mofetil for the treatment of adult patients with active class III, IV or V (including mixed class III/V and IV/V) lupus nephritis (LN)".

Role in the care pathway?

LUPKYNIS (voclosporin) does not have a role in the care pathway in view of its poorly established efficacy.

Transparency Committee's Conclusions

Clinical Benefit

- Active lupus nephritis is a rare, serious disease, that can lead to severe even end-stage renal failure and be life-threatening.
- 7.9 mg (voclosporin), soft capsule is a symptomatic medicinal product.
- The efficacy/adverse effect ratio is poorly established due to considerable uncertainty about the effect of voclosporin versus placebo. In fact, the standard treatment used as an *add-on* to the experimental treatment or the placebo (*see* AURORA-1 study design) has serious limitations in terms of extrapolation to the standard of care according to French practice (scheme to reduce corticosteroids to very low doses, low use of synthetic antimalarials, no measurement or adjustment of MMF and hydroxychloroquine). In addition, subgroup analyses and interaction tests showed an interaction associated with a history of treatment with MMF or not. There is no information indicating whether treatment of patients with MMF was failing and therefore whether or not they received optimal treatment in the placebo group.
- There are medicinal alternatives to this medicinal product.
- In view of its poorly established efficacy, LUPKYNIS (voclosporin) does not have a role in the therapeutic strategy of the treatment of active lupus nephritis in combination with MMF.

- **Public health benefit:**

In view of:

- the severity of the disease which degrades patients' quality of life and which can be life-threatening,
- its low prevalence,
- the partially met medical need identified,
- the absence of response to the need identified due to:
  - the absence of additional impact on morbidity and mortality or on quality of life,
  - the absence of proven impact on the organisation of care and the patient's care pathway and life course, particularly the absence of demonstration in terms of reduction of the use of dialysis and kidney transplantation and reduced mortality,

LUPKYNIS (voclosporin) is not liable to have an additional impact on public health.

In view of all of these elements, the Committee considers that the clinical benefit provided by LUPKYNIS 7.9 mg (voclosporin), soft capsule is insufficient in the MA indication to be covered by national solidarity schemes given the available alternatives.

The Committee gives an unfavourable opinion on the inclusion of LUPKYNIS 7.9 mg (voclosporin), capsules on the list of medicinal products reimbursable to persons insured under social security schemes and on the list of medicinal products approved for the use of communities in the MA indication and at the MA doses.