SUMMARY

sodium zirconium cyclosilicate

LOKELMA 5 g and 10 g

powder for oral suspension

First listing

Original French opinion adopted by the Transparency Committee on 24 April 2024

The legally binding text is the original French opinion version

Summary of opinion

Favourable opinion for reimbursement in the "treatment of hyperkalaemia in adult patients".

Transparency Committee's conclusions

Clinical Benefit

- Hyperkalaemia can cause cardiac disorders that may be life-threatening for the patient.
- This is a curative medicinal product for hyperkalaemia (limited to 72 hours of treatment) and a preventive medicinal product for recurrences of hyperkalaemia as long-term maintenance therapy.
- The efficacy/adverse effects ratio is high in the MA indication.
- It is a first-line treatment for hyperkalaemia in adult patients, except in cases of emergency treatment for life-threatening hyperkalaemia.

Public health benefit

Considering:

- the severity of hyperkalaemia, which can cause serious cardiac disorders;
- the frequency of hyperkalaemia, particularly in patients with renal impairment or heart failure;
- the medical need partially met by the cation exchange resins currently available;
- the partial response to the identified need given:
  - evidence of an additional impact on the reduction and normalisation of serum potassium levels in adult patients with chronic hyperkalaemia or in cases where serum potassium levels can be gradually lowered;
  - but the lack of evidence of an additional impact on morbidity and mortality and on quality of life;

LOKELMA (sodium zirconium cyclosilicate) is unlikely to have an additional impact on public health.

Considering all these elements, the Committee deems that the clinical benefit of LOKELMA (sodium zirconium cyclosilicate) 5 g and 10 g powder for oral suspension is substantial in the MA indication.

The Committee issues a favourable opinion for inclusion of LOKELMA (sodium zirconium cyclosilicate) 5 g and 10 g powder for oral suspension in both the list of covered drugs for outpatients and the list of covered drugs for inpatients approved for use in the MA indication and at the MA dosages.

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

Clinical Added Value

Considering:

- demonstration of the efficacy of LOKELMA (sodium zirconium cyclosilicate) compared to placebo on the reduction and normalisation of serum potassium levels during the correction phase and the prevention of recurrences of hyperkalaemia during the maintenance phase;
- a safety profile judged to be acceptable despite the frequent occurrence of adverse events related to oedema;
- the insipid flavour of LOKELMA (sodium zirconium cyclosilicate) and the absence of sorbitol in its composition, which, according to expert opinion, could favour compliance and safety, respectively, in treated patients;
- a partially met medical need;

but in view of:

- the absence of a direct comparison with cation exchange resins;
- the absence of data concerning clinically relevant morbidity and mortality endpoints;
- the selection of a majority of patients included in clinical trials with serum potassium levels of 5.1 to 5.5 mmol/L;

the Committee deems that LOKELMA (sodium zirconium cyclosilicate) 5 g and 10 g powder for oral suspension provides a minor clinical added value (CAV IV) in the current care pathway for the treatment of hyperkalaemia in adults.

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