OPINION ON MEDICINAL PRODUCTS

patiromer
VELTASSA 8.4 and 16.8 g

Powder for oral suspension

Reassessment

Adopted by the Transparency Committee on 14 September 2022

SUMMARY

The legally binding text is the original French opinion version

- **Electrolyte disorders**
- **Sectors: Community and Hospital**

Key points

Approval of reimbursement for the treatment of hyperkalaemia in adults.

Therapeutic improvement?

No therapeutic improvement.

Role in therapeutic strategy?

For the long-term treatment of hyperkalaemia or in cases in which gradual blood potassium reduction is possible, a low-potassium diet, thiazide diuretics or loop diuretics, gastrointestinal potassium exchange resins and/or where applicable, reduction or discontinuation of potassium-elevating medicinal products (RAAS inhibitors) are recommended. The aim of long-term treatment is to prevent recurrences of hyperkalaemia by correcting modifiable underlying causes (such as sources of potassium intake or metabolic acidosis), and by controlling the serum potassium concentration.

Role of VELTASSA (patiromer) in the therapeutic strategy:

The new data submitted based essentially on exploratory analyses and on observational studies are not likely to modify the Committee's previous assessment of VELTASSA (patiromer) (see CT opinion of 20/02/2019).

VELTASSA (patiromer) is a first-line treatment for hyperkalaemia, in the same way as the other cation-exchange resins available.

The Committee upholds its opinion that, although VELTASSA (patiromer) may have a different taste to other cation-exchange resins, no comparative clinical study has been carried out to demonstrate its superiority over these alternatives in terms of improving compliance or quality of life. In addition, VELTASSA (patiromer) proprietary medicinal products contains sorbitol as part of the counterion complex (4 g per 8.4 g of patiromer). It should be noted that the other cation-exchange resins available (KAYEXALATE and RESIKALI) have been the subject of warnings and precautions for use when associated with sorbitol (to prevent constipation) due to rare cases of onset of intestinal necrosis. No cases of colonic necrosis have been reported in clinical studies with VELTASSA (patiromer). The duration of the studies (not more than 52 weeks), and the number of patients included are insufficient to rule out this risk given the rareness of this complication; however, international pharmacovigilance data have not demonstrated any new signals to date.

Committee's conclusions

Actual Clinical Benefit

- Hyperkalaemia may cause life-threatening heart disorders, in particular among adult patients with chronic kidney failure (not treated with dialysis), associated with heart failure.
- The proprietary medicinal product VELTASSA (patiromer) remains a curative treatment for hyperkalaemia.
- The efficacy/adverse effect ratio remains significant in the marketing authorisation indication, without differentiating comorbidity criteria.
- Alternative medications are available, particularly other cation-exchange resins (KAYEXALATE and RESIKALI).
- The proprietary medicinal product VELTASSA (patiromer) remains a first-line medicinal product.

➔ Public health benefit

Considering:

- the severity of hyperkalaemia, potentially causing severe heart disorders, in particular among adult patients with chronic kidney failure associated with heart failure, not suitable for RAAS inhibitor treatments at appropriate doses,
- the medical need for effective and better-tolerated new cation-exchange resins, but the lack of additional response of VELTASSA (patiromer) to the medical need, failing comparative data with respect to available cation-exchange resins from the response,
- the impact of VELTASSA (patiromer) on blood potassium reduction and control after normalisation and on hyperkalaemia recurrence prevention,
- the lack of demonstrated impact on morbidity-mortality, quality of life, and on the delivery of care (reduction of hospital admissions) with respect to the alternatives available,

VELTASSA (patiromer) is not likely to have an additional impact on public health.

Considering all of these elements, the Committee deems that the actual clinical benefit of VELTASSA (patiromer) remains significant in the marketing authorisation indication, namely the treatment of hyperkalaemia in adults.

The Committee approves inclusion in the list of proprietary medicinal products qualifying for reimbursement under social security and in the list of proprietary products approved for community use for the marketing authorisation indication and at the marketing authorisation dosages.

Recommended reimbursement rate: 65%

Clinical Added Value

There is a medical need for effective and better-tolerated new cation-exchange resins. The safety profile of VELTASSA (patiromer) reported in the clinical trials was consistent with the international pharmacovigilance follow-up available to date. However, the new data submitted based essentially on exploratory analyses and on observational studies are not likely to modify the Committee's previous assessment of VELTASSA (patiromer). Hence, VELTASSA (patiromer) provides no clinical added value (CAV V) for the current therapeutic strategy for the management of hyperkalaemia in adults, which includes cation-exchange resins and diuretics.