Patiromer (Veltassa®) for the treatment of hyperkalaemia in adults

Summary of recommendations by *Zorginstituut Nederland* (National Health Care Institute, the Netherlands) dated 25 February 2019

Zorginstituut Nederland carried out an assessment of the medicinal product patiromer (Veltassa®), whereby they came to the following conclusion.

In a letter dated 9 July 2018 (CIBG-18-06564), the Minister of Health, Welfare and Sport (VWS) asked *Zorginstituut Nederland* to assess whether patiromer (Veltassa®) is interchangeable with a drug currently included in the Medicine Reimbursement System (GVS). The *Zorginstituut* has completed its assessment.

The manufacturer has asked for inclusion on List 1B of the Health Insurance Decree.

Patiromer (Veltassa®) is registered for the treatment of hyperkalaemia in adults. The manufacturer is asking for reimbursement for a sub-group within the broad indication for which patiromer is registered, i.e., patients with chronic kidney disease (CKD) stage 3 or 4 with chronic hyperkalaemia which requires treatment with RAAS inhibitors.
Patiromer is available as a powder for oral suspension. Each sachet contains 8.4 g, 16.8 g or 25.2 g. The starting dose is 8.4 g once daily. This dose may be adjusted in intervals of one week or longer, based on the serum potassium levels and the desired target range. The daily dose may be increased or decreased by 8.4 g, as necessary to reach the desired target range. The maximum dose is 25.2 g patiromer once daily.

Outcome of the assessment
The findings in the GVS report and the corresponding pharmacotherapeutic report show that an indirect comparison of patiromer with a low-dose (sorbitol free) sodium polystyrene sulfonate (SPS) and a low-dose (sorbitol free) calcium polystyrene sulfonate (CPS) is difficult due to differences in study design, patient characteristics, outcome parameters and follow-up duration. All three drugs seem able to reduce serum potassium levels consistently and thus permit the continued use of RAAS inhibitors. The undesired effects of patiromer, SPS and CPS are fairly similar and relate mainly to metabolism and nutrition disorders, such as magnesium deficiency and gastrointestinal disorders such as constipation, diarrhoea, nausea and vomiting.

Zorginstituut Nederland concludes that the therapeutic value of patiromer for the treatment of hyperkalaemia in adults with chronic kidney disease who require treatment with RAAS inhibitors is the same as that of CPS and SPS.

Assessment of interchangeability
As patiromer, similarly to CPS, is a cation exchange polymer that exchanges potassium for calcium, in view of the current classification in the GVS, its interchangeability can in principle be considered.
Based on the criteria of interchangeability, patiromer powder can be regarded as interchangeable with the potassium-binder calcium polystyrene sulfonate (CPS) which has already been included on List 1B of the GVS.

Advice
On this basis, we advise the Minister of VWS to include patiromer together with

CPS in a new cluster on List 1A of the GVS. The applicable standard dose for patiromer is 8.4 g/day. The standard dose of CPS is 45 g/day. Should the Minister decide to include this product in the GVS, we advise linking its reimbursement to the following condition.

Condition
Only for an insured person aged eighteen years or older, with chronic kidney disease (CKD) stage 3 or 4, with chronic hyperkalaemia that requires treatment with RAAS inhibitors.

For further information, please contact: JBoer@zinl.nl; warcg@zinl.nl

The original text of this excerpt from advice of Zorginstituut Nederland was in Dutch. Although great care was taken in translating the text from Dutch to English, the translation may nevertheless have resulted in discrepancies. Rights may only be derived on the basis of the Dutch version of Zorginstituut Nederland's advice.
Furthermore, Zorginstituut Nederland points out that only the summary of this report was translated. A proper understanding of all relevant considerations and facts would require familiarity with the Dutch version of this report, including all appendices.