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Our reference

2022034178

Date 1 February 2023
Subject Extension of further conditions for patiomer (Veltassa®) through the
cancellation of the List 2 conditions of the Health Insurance
Regulation

Dear Mr Kuipers,

In your letter of 31 October 2022 (CIBG-22-04609), you asked the National Health Care Institute to advise you on the cancellation of the List 2 condition for patiomer (Veltassa®). The National Health Care Institute has now completed the substantive assessment. The considerations are set out in the annex.

Background

Patiomer is registered for the treatment of hyperkalaemia in adults. Patiomer is a cation-exchange polymer. Currently, four cation-exchange polymers are registered in the Netherlands, namely calcium polystyrene sulphonate (CPS, Sorbisterit®), sodium polystyrene sulphonate (SPS, Resonium®) and sodium zirconium cyclosilicate (NZC, Lokelma®). Based on previous assessments of the National Health Care Institute, patiomer has been placed on List 1A of the GVS, where it is clustered with CPS (cluster 0V03AEBO V). The present further conditions for patiomer are set out in List 2 and are as follows:

Only for insured persons of eighteen years or older with chronic kidney damage CKD stage 3 or 4 with chronic hyperkalaemia who require treatment with RAAS inhibitors.

The above condition was established in 2019 on the basis of the reimbursement application of a subgroup within the registered indication. The marketing authorisation holder now applies for reimbursement for the entire registered indication and thus for the List 2 condition to be dropped. The other registered cation exchange polymers CPS, SPS and NZC do not have List 2 conditions.

Substantive assessment

Pharmacotherapy

Various studies show that patiomer, like SPS, CPS and NZC, is able to reduce potassium levels in all hyperkalaemia patients. For example, this allows continued treatment with RAAS inhibitors (renin angiotensin aldosterone system inhibitors, including angiotensin converting enzyme [ACE] inhibitors, angiotensin receptor blockers [ARBs] or aldosterone antagonists) in non-dialysis patients. On the basis of the information in the annex, the National Health Care Institute concludes that patiomer in the treatment of hyperkalaemia in adults meets the established medical science and medical practice.

Budget impact analysis

The cancellation of the List 2 condition of patiromer is not expected to be accompanied by additional costs charged to the pharmaceutical budget. There will only be a shift in the number of users per medicinal product within the cluster.

Advice from the National Health Care Institute

Patiromer is already included on List 1A of the GVS (cluster 0V03AEBO) with further conditions. Based on the above considerations, the National Health Care Institute advises amending List 2 of the Healthcare Insurance Regulations. The List 2 condition for patiromer can be cancelled. The cancellation of the further conditions is not expected to be accompanied by additional costs.

Yours sincerely,

Sjaak Wijma
Chairperson of the Executive Board

Annex 1: Substantive assessment

