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Minister of Medical Care and Sports PO Box 20350 2500 EJ THE HAGUE

2021004453

Date 12 February 2021

Subject GVS advice sodium zirconium cyclosilicate (Lokelma®)

Dear Ms van Ark,

In your letter of 10 August 2020 (CIBG-20-0803), you asked the National Health Care Institute to assess whether sodium zirconium cyclosilicate (Lokelma®) is interchangeable with a product that is included in the Medicine Reimbursement System (GVS). The National Health Care Institute has since completed its assessment. The considerations are included in the GVS report attached to this letter.

Sodium zirconium cyclosilicate (Lokelma \circledR) is registered for the treatment of hyperkalemia in adults. Sodium zirconium cyclosilicate is available as a powder for oral suspension. Each sachet contains 5 g or 10 g.

Dosage of sodium zirconium cyclosilicate

Correction phase: The dosage in the correction phase is 10 g, three times a day.

Maintenance phase: The recommended starting dose is 5 g once a day, which can be increased as needed to 10 g once a day or reduced to 5 g every other day. The maximum dosage is 10 mg per day.

Chronic haemodialysis: Sodium zirconium cyclosilicate must only be administered on days without dialysis, with 5 g once a day as the initial dose. The dose can be adjusted at weekly intervals in increments of 5 g to a maximum of 15 g once a day on non-dialysis days.

The standard dose for sodium zirconium cyclosilicate can be set at 7.5 g per day.

Review of interchangeability

The usual pharmaco-therapeutic treatment that sodium zirconium cyclosilicate (Lokelma®) can be compared to consists of the resin preparations sodium polystyrene sulphonate (SPS, Resonium®) and calcium polystyrene sulphonate (CPS, Sorbisterit®). In addition, since 2019, the cation-exchange polymer patiromer (Veltassa®) has been included in the GVS.

Given that the effect of sodium zirconium cyclosilicate, like SPS, is based on the exchange of potassium with sodium, the present classification in the GVS means

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Our reference 2021004453 that SPS is considered to be comparable to sodium zirconium cyclosilicate.

Conclusion of the pharmaco-therapeutic report

National Health Care Institute has concluded that sodium zirconium cyclosilicate has an equal value compared to sodium polystyrene sulphonate (SPS).

Advice on inclusion in the GVS

National Health Care Institute recommends that you include sodium zirconium cyclosilicate (Lokelma®), together with sodium polystyrene sulphonate (SPS), on List 1A of the GVS, in a newly formed cluster. The standard dose for sodium zirconium cyclosilicate can be set at 7.5 g per day. The standard dose for SPS is 45 g per day.

Yours sincerely,

Sjaak Wijma Chair of the Executive Board

National Health Care Institute

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Date

11 February 2021

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