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Our reference
2020047256

Date 16 November 2020
Subject GVS advice Mayzent® (siponimod)

Dear Ms van Ark,

In your letter of 9 June 2020 (CIBG-20-0554), you requested the National Health Care Institute to carry out a substantive review of whether siponimod (Mayzent®) is interchangeable with a product that is included in the medication reimbursement system (GVS). The National Health Care Institute has recently completed its assessment. The considerations are included in the GVS report attached to this letter.

Mayzent® is indicated for the treatment of adult patients with secondary progressive multiple sclerosis (SPMS) with active disease evidenced by relapses or imaging features of inflammatory activity.

Conclusion of the pharmaco-therapeutic report
National Health Care Institute has come to the final conclusion that in the treatment of active SPMS, siponimod has an equal value compared to fingolimod.

Review of interchangeability
Based on the criteria for interchangeability, it can be concluded that siponimod (Mayzent®) is interchangeable with the second-line MS products in the GVS cluster 0L01BBCO V: fingolimod and cladribine.

Standard dose
Mayzent® is available as a film-coated tablet; each tablet contains siponimod fumaric acid equivalent to 0.25 mg or 2 mg siponimod. The maintenance dose is 2 mg siponimod per day; the standard dose can be set at 2 mg per day.

Advice on inclusion in the GVS
National Health Care Institute recommends that siponimod (Mayzent®) be included in List 1A in cluster 0L01BBCO V with a standard dose of 2 mg. National Health Care Institute also recommends the inclusion of siponimod (Mayzent®) on List 2 of the Health Insurance Regulation (Rzv) and imposing the conditions stated below.

Condition siponimod
Only for an insured person aged 18 years or older with active secondary progressive multiple sclerosis (SPMS) evidenced by relapses or imaging features of inflammatory activity and who has not responded to treatment with at least one disease-modifying medicinal product registered for the treatment of MS.

Yours sincerely,

Sjaak Wijma
Chair of the Executive Board

National Health Care Institute
Care II
Infectious Diseases, Blood & Immunology

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