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Minister of Medical Care and Sport
PO Box 20350
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2022006224

Date 22 February 2022
Subject GVS advice cenobamate (Ontozry®)

**National Health Care
Institute**

Care
Medicinal Products

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Our reference

2022006224

Dear Mr Kuipers,

In your letter of 5 January 2022 (CIBG-21-03111), the State Secretary of Health, Welfare and Sport requested the National Health Care Institute to assess whether the medicinal product cenobamate (Ontozry®) is interchangeable with a product that is included in the Medicine Reimbursement System (GVS). The National Health Care Institute has now completed the substantive assessment. The considerations are included in the GVS report attached to this letter.

Cenobamate is indicated for the adjunctive treatment of focal-onset seizures with or without secondary generalisation in adult patients with epilepsy who have not been adequately controlled despite a history of treatment with at least 2 anti-epileptic medicinal products. Cenobamate (Ontozry®) 12.5 mg is available in tablet form. Cenobamate 25 mg, 50 mg, 100 mg, 150 mg and 200 mg are available in film-coated tablet form. The recommended starting dose of cenobamate is 12.5 mg per day, gradually titrated to the recommended target dose of 200 mg per day. Based on the clinical response, the dose can be increased to a maximum of 400 mg per day.

The outcome of the assessment

The National Health Care Institute has concluded that cenobamate meets the established medical science and medical practice as the adjunctive treatment of focal-onset seizures with or without secondary generalisation in adult patients with epilepsy who have not been adequately controlled despite a history of treatment with at least 2 anti-epileptic medicinal products. Based on the available data, cenobamate has an equal value compared to the group of secondary preferred adjuvants brivaracetam, gabapentin, perampanel, pregabalin, topiramate and zonisamide.

Review of interchangeability

Based on the criteria for interchangeability, it can be concluded that cenobamate (Ontozry®) is interchangeable with the other medicinal products in the GVS cluster 0N03AXEO V, which includes: perampanel and topiramate.

Advice

On the basis of the above, we advise you to include cenobamate (Ontozry®) in List 1A in the ON03AXEO V cluster with perampanel and topiramate. The standard dose for cenobamate can be set at 200 mg.

Yours sincerely,

Sjaak Wijma
Chair of the Executive Board

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