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To the Minister of Health, Welfare and Sport
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2025005284

**National Health Care
Institute**

Care
Medicinal Products

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Contact

K. Watson
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Date 28 February 2025
Re: GVS advice rimegepant (Vydura®) for acute migraine treatment

Our reference
2025005284

Dear Ms Agema,

The National Health Care Institute advises you on the inclusion of rimegepant (Vydura®) in the Medicines Reimbursement System (GVS) for the acute treatment of migraine. This advisory report was prompted by your request in the letter dated 2 December 2024 (CIBG-24-07588).

Migraine is a condition with severe headache attacks. In the Netherlands, some 2 million people are regularly affected by migraine. It is most common among women between 40 and 54 years. A migraine attack occurs because something goes wrong in the nervous system. First, the blood vessels in the head tighten, and then they expand strongly. The vasodilation causes the headache. The attacks can last 4 to 72 hours and affect daily activities. Approximately one-third of patients may experience an aura prior to or during a migraine attack, where they see light flashes or dark spots and/or experience tingling in a hand, arm or around the mouth. These symptoms will pass when the headache begins. This is usually within an hour. In an acute migraine attack, the focus is on analgesia; first with 'regular' painkillers (e.g. paracetamol or ibuprofen). If they do not help, general practitioners often prescribe medicines that have an effect on the blood vessels in the head: triptans (= 5HT1 agonists). Rimegepant could possibly be used if these medicinal products also do not adequately control the migraine attack.

Recorded indications

Rimegepant is indicated for the

- acute treatment of migraine with or without aura in adults;
- preventive treatment of episodic migraine in adults who have at least 4 migraine attacks per month.

Claim by the marketing authorisation holder

Rimegepant has a therapeutic benefit over placebo for the acute treatment of migraine with or without aura as final-line treatment in adults for whom prior treatment with three or more 5HT1 agonists¹ has failed, or who are intolerant for

¹ The guideline of the Dutch College of General Practitioners (NHG) describes 5HT1 agonists as triptans.

or have contraindications for 5HT1 agonists.

The MAH only requests inclusion in List 1B of the Health Insurance Regulation for the acute treatment of migraine with or without aura in adults. Preventive treatment of episodic migraine is outside the scope of this assessment.

Advice

The National Health Care Institute recommends that rimegepant not be included in the GVS for the acute treatment of migraine with or without aura in adults.

Substantive assessment

Despite the MAH claim, they did not submit data on the effectiveness of rimegepant on migraine patients who have failed treatment with at least three 5HT1 agonists. The product also appeared not to have been studied. It was therefore not possible to assess the effectiveness in this particular patient population. In addition, rimegepant has not been studied in a population sufficiently similar in patient characteristics to the Dutch population. The seizure treatment in the USA and Asia studies was significantly different from that in the Netherlands, while in those studies less than 10% of patients had failed treatment with at least two 5HT1 agonists. Therefore, the data and results of these studies are not useful for the scientific assessment of the effectiveness of rimegepant in Dutch patients with migraine after having failed treatment with at least three 5HT1 agonists. For these reasons, the National Health Care Institute, supported by its Scientific Advisory Board (WAR), has determined that rimegepant does not comply with the established medical science and medical practice for the present indication.

Should you need any further information, please do not hesitate to contact us. The pharmacotherapeutic report is attached .

Yours sincerely,

M.J. Janssen
Chairperson of the Executive Board

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