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2025014379

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Date 26 June 2025
Re: additional GVS advice - List 2 conditions CGRP inhibitors

Our reference
2025014379

Dear Ms Jansen,

In our letter of 12 March 2025, we advised your predecessor on the expansion of the reimbursement of the subcutaneous CGRP inhibitors erenumab (Aimovig®), galcanezumab (Emgality®) and fremanezumab (Ajovy®) for the prevention of episodic migraine (EM). This advisory report was prompted by a request in the letter of 2 September 2024 (CIBG-24-07333).

The letter of 12 March did not mention any List 2 conditions for the Health Insurance Regulation because the National Health Care Institute was still consulting with the field parties.

The List 2 conditions for these medicinal products are currently as follows:

Current condition **erenumab, fremanezumab, galcanezumab (and atogepant):**
"only for an insured person aged 18 years and older with chronic migraine after exclusion or treatment of medication overuse headache and after failure of prophylactic treatment with

a. *at least two months of topiramate or valproate in adequate doses and*
b. *at least two attempts with botulin toxin A (6 months) in accordance with the PREEMPT protocol,*

unless it is an insured person with chronic migraine who had already been treated with a CGRP inhibitor under a managed access programme prior to 17 September 2021."

With this letter, we advise you to include the following List 2 condition for erenumab, fremanezumab and galcanezumab in the Health Insurance Regulation. These conditions should replace the current conditions. The List 2 condition of atogepant should remain unchanged.

New condition for **erenumab, fremanezumab, galcanezumab:**
"Only for an insured person with episodic migraine with at least 4 migraine days per month after failure of prophylactic treatment with the following 5 categories of migraine prophylactic agents (regardless of sequence):

a. *angiotensin receptor blocker, and*
b. *β-blocker, and*

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c. *tricyclic antidepressant, and*
d. *topiramate or valproate, and*
e. *calcium receptor antagonist.*

Only for an insured person with chronic migraine after exclusion or treatment of medication overuse headache and after failure of prophylactic treatment with (regardless of sequence):

a. *topiramate or valproate, and*
b. *at least two attempts with botulin toxin A (6 months) in accordance with the PREEMPT protocol*

unless it is an insured person with chronic migraine who had already been treated with a CGRP inhibitor under a managed access programme prior to 17 September 2021.

In addition, the following applies for both episodic migraine and chronic migraine:

- *All treatment steps should be performed at an appropriate dosage and with a minimum treatment duration in accordance with the applicable treatment guidelines before starting a CGRP-MAB.*
- *Treatment steps can only be skipped in case of contraindications and can be discontinued prematurely in case of adverse effects.*
- *An insured person with at least 4 migraine days per month who has previously been treated with a CGRP-mAbs for migraine does not need to go through the above treatment steps again.*
- *Both the indication, treatment and prescription of CGRP-mAbs is reserved for (or falls under the responsibility of) a neurologist."*

We would like to note that the above List 2 conditions do not lead to a different therapeutic value, a different budget impact analysis or a different cost-effectiveness. This is fully in line with the assessment carried out by the National Health Care Institute.

Yours sincerely,

M.J. Janssen
Chairperson of the Executive Board