Zorginstituut Nederland

> Return address PO Box 320, 1110 AH Diemen

To the Minister of Health, Welfare and Sport
P.O. Box 20350
2500 EJ THE HAGUE

2025025391

National Health Care Institute
Research, Development and Medicinal Products
Medicinal Products Team

Willem Dudokhof 1
1112 ZA Diemen
PO Box 320
1110 AH Diemen
www.zorginstituutnederland.nl
info@zinl.nl

T +31 (0)20 797 85 55

Contact
K. Watson
warcg@zinl.nl

Our reference
2025025391

Date 22 October 2025
Re: Expansion of additional condition for atogepant (Aquipta®) for episodic migraine

Dear Mr Bruijn,

The National Health Care Institute advises you on the extension of the List 2 condition for the application of atogepant in the prevention of episodic migraine. This advice was prompted by your request in the letter of 15 July 2025 (CIBG-25-08443).

Migraine is a condition with intense headache attacks. In the Netherlands, approximately 2 million people are regularly affected by migraine. It is most common among women between the ages of 40 and 54 years. Migraine attacks can last for 4 – 72 hours, and limit daily activities. Approximately one-third of these people may experience an aura before or during a migraine attack, in which they see flickering stars 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 episodic migraine (EM), seizures are less frequent than in chronic migraine (CM). The severity of the symptoms is the same in both forms. EM can change to CM and vice versa. The distinction is important, because it determines the choice of treatment options. Atogepant is a medicine that can be swallowed as a tablet. It can be used in people with migraine who have at least 4 migraine days per month. They suffer from frequent headaches.

Licensed indication
Atogepant (Aquipta®) is indicated for the prophylaxis of migraine in adults who have at least 4 migraine days per month and is available in 10 and 60 mg tablets

Current condition atogepant:
Only for an insured person aged 18 years and older with chronic migraine after exclusion or treatment of medication-overuse headache and 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.

National Health Care Institute
Research, Development and Medicinal Products
Medicinal Products Team

Date
22 October 2025

Our reference
2025025391

Claim by the marketing authorisation holder
Atogepant (Aquipta®) has a similar therapeutic value to the subcutaneous CGRP-mAbs (erenumab, fremanezumab and galcanezumab) in adults patients with EM with at least 4 migraine days per month, after failure on treatment with the 5 categories of migraine prophylactics listed in the current guideline: angiotensin receptor blocker (candesartan), beta blockers (metoprolol or propranolol), anti-epileptics (topiramate or valproate), calcium-receptorantagonist (flunarizine), and tricyclic antidepressant (amitriptyline).

Background

The subcutaneous CGRP-mAbs (erenumab, fremanezumab and galcanezumab) have been reimbursed for CM under specific conditions since November 2021. On 23 October 2024, the National Health Care Institute advised that atogepant (Aquipta®) for CM should also be included in List 1B of the GVS.[1] Atogepant has been part of the health insurance package since 1 December 2024 and, as such, is reimbursed for CM under the same additional conditions and appropriate use arrangements that apply to the subcutaneous CGRP-mAbs.[2] On 12 March 2025, the National Health Care Institute advised your predecessor to include the subcutaneous CGRP-mAbs in the health insurance package for EM as well.[3] On 26 June 2025, the National Health Care Institute advised your predecessor to expand the existing additional conditions in this context.[4]

Advisory report

The National Health Care Institute recommends to include atogepant for EM in the health insurance package under exactly the same additional conditions and appropriate use arrangements as for the subcutaneous CGRP-mAbs[3], which the National Health Care Institute recommended in the additional GVS advice on this issue dated 26 June 2025.[4] Since the value of atogepant and the subcutaneous CGRP-mAbs is equal for EM, the inclusion of atogepant in the health insurance package for EM should not lead to additional costs to the pharmaceutical budget, as stated in the reimbursement advice for the subcutaneous CGRP-mAbs for EM.[3]

We have explained below how we prepared this advice.

Substantive assessment

Therapeutic value

Based on the study results of atogepant described in the pharmacotherapeutic report, the National Health Care Institute concluded that atogepant as prophylaxis for EM is equivalent to the subcutaneous CGRP-mAbs and thus complies with the established medical science and medical practice.

Budget impact analysis

In the reimbursement advice for the subcutaneous CGRP-mAbs dated 12 March 2025, the budget impact in year 3 after the reimbursement decision was calculated based on the current costs of the medicinal products. On the basis of the list prices, the National Health Care Institute recommended a discount of at least 25% in order to reach a socially acceptable price. In the budget impact

[1] GVS advice atogepant (Aquipta®) dated 23 October 2024; ref. 2024035726

[2] Govt Gazette 2024, no. 38352.

[3] GVS advice expansion of additional condition of CGRP inhibitors dated 12 March 2025; ref. 2025005350

[4] Additional GVS advice List 2 conditions CGRP inhibitors dated 26 June 2025; ref. 2025014379

National Health Care Institute
Research, Development and Medicinal Products
Medicinal Products Team

Date
22 October 2025

Our reference
2025025391

analysis (BIA) for atogepant, the National Health Care Institute assumed that price arrangements would be made with their marketing authorisation holders and that their actual prices will be lower. However, these are not public. Because the list price for atogepant provided by the marketing authorisation holder to the National Health Care Institute is already lower than the list prices of the subcutaneous CGRP-mAbs in the BIA in the reimbursement advice dated 12 March 2025, the list price for atogepant was used in the attached BIA. Assuming that in year 3 after the reimbursement decision, approximately 3607 EM patients will be treated with atogepant or a subcutaneous CGRP-MAB, the budget impact for the three subcutaneous CGRP-mAbs and atogepant together is €14.9 million. Since atogepant can be taken orally, more EM patients may want to be treated than is currently the case. This is especially true for patients who do not want to be treated with a subcutaneous CGRP-mAb due to a (severe) fear of needles. However, this is very uncertain. This is also the case for the total treatment duration. Inclusion of atogepant to the health insurance package will only lead to substantial additional costs if its introduction leads to above-average growth of the overall market for CGRP inhibitors; for example, through a significant, (as yet) unforeseen inflow of EM patients. The National Health Care Institute does not consider this likely.

Should you need any further information, please do not hesitate to contact us. The assessment reports have been added as annexes (pharmacotherapeutic report and budget impact analysis).

Yours sincerely,

K.C. Timm-van Ruitenburg
Member of the Executive Board