Health Technology Briefing
May 2026

Atogepant for the prevention of menstrual migraine

Company/Developer	AbbVie Ltd

☐ New Active Substance ☒ Significant Licence Extension (SLE)

NIHRIO ID: 40198	NICE ID: Not available	UKPS ID: 675357

Licensing and Market Availability Plans

Currently in Phase III clinical development

Summary

Atogepant is being developed to prevent menstrual migraine in female adults. Migraine is a type of headache that can cause moderate to severe throbbing pain, usually on one side of the head. It is commonly accompanied by nausea and sensitivity to light and sound. Menstrual migraine is most likely to occur in the two days leading up to a period and the first three days of bleeding. These attacks are often longer and more severe than non-menstrual migraine attacks. The burden of menstrual migraine is significant for many women as it can disrupt daily activities and lead to increased stress and anxiety. Risk of migraine is influenced by various factors like lifestyle, genetic makeup and environmental factors. Migraine cannot be cured, but treatment can help prevent attacks and manage symptoms when they occur. Some medicines used to prevent migraine were originally developed for other conditions and may not work well for everyone. They can also cause side effects in some people, which may make them harder to take regularly.

Atogepant is an oral drug given once a day. Atogepant helps prevent menstrual migraine by blocking CGRP, a protein in the body involved in migraine pain. Hormonal changes around a period, particularly the drop in oestrogen are thought to influence CGRP (pain) signalling and may contribute to migraine attacks. Atogepant is generally well tolerated and may be a better option for those who struggle with side effects from other treatments. If approved, atogepant will provide a new, CRGP-targeted option for prevention of menstrual migraine in adults.

This briefing reflects the evidence available at the time of writing and a limited literature search. It is not intended to be a definitive statement on the safety, efficacy or effectiveness of the health technology covered and should not be used for commercial purposes or commissioning without additional information. A version of the briefing was sent to the company for a factual accuracy check. The company was available to comment.
Copyright © National Institute for Health and Care Research Innovation Observatory, The University of Newcastle upon Tyne.

Proposed Indication

For the preventive treatment of menstrual migraine in adults.[1]

Technology

Description

Atogepant (AQUIPTA) is an orally administered, small molecule, selective calcitonin gene-related peptide (CGRP) receptor antagonist that blocks the binding of the CGRP to the receptor and antagonizes CGRP receptor function. CGRP is a neuropeptide that has been associated with migraine pathophysiology. In the trigeminovascular system, CGRP modulates nociceptive signalling and inflammation, and also functions as a vasodilator.[2]

Atogepant is currently in clinical development for the prevention of menstrual migraine in female adults. In phase III clinical trial (NCT06806293), participants are randomly assigned to one of the 2 treatment groups to receive oral atogepant or matching placebo for 3 menstrual cycles during the double-blind period. During the open-label treatment period, participants will receive atogepant during each menstrual cycle.[1]

Key Innovation

There is significant need for effective and tolerable treatments for people with migraine. People with menstrual migraine are often treated similarly to people without menstrual migraine; however, people with menstrual migraine experience more severe, disabling, and prolonged attacks than people with non-menstrual migraine for which they are also less responsive to treatment. Approximately two thirds of females with migraine may experience menstrual migraine; however, the prevalence of menstrual migraine is often underreported and there is a lack of awareness regarding the condition.[3]

Atogepant is the first oral CGRP receptor antagonist specifically developed for migraine prevention.[4] Key mechanisms and sites of action for medications used in migraine prevention remain unclear, it seems that almost all affect the trigeminal CGRP system indirectly.[5] CGRP-related therapies are designed to act on the trigeminal pain system, making them more targeted than broader non-specific preventive treatments and are generally associated with relatively few adverse effects.[6] Evidence strongly suggests that oestrogen fluctuations are involved in migraine attacks worsening during the perimenstrual window through several mechanisms directly or indirectly involving the CGRP pathway. CGRP receptor antagonists could represent a safe and effective preventive therapeutic strategy able to reduce the disabling burden of menstrual migraine attack frequency, duration, intensity, and significantly improve the response to painkillers.[7] Atogepant is administered orally, reaching maximum plasma concentrations by 1 to 2 hours, with a half-life of approximately 11 hours.[8]

If approved, atogepant will provide a novel option for prevention of menstrual migraine in adults.

Regulatory & Development Status

Atogepant currently has Marketing Authorisation in the EU/UK for:

- prophylaxis of migraine in adults who have at least 4 migraine days per month.[2]
- acute treatment of migraine with or without aura in adults.[9]

Copyright © National Institute for Health and Care Research Innovation Observatory, The University of Newcastle upon Tyne.

Patient Group

Disease Area and Clinical Need

Migraine is a common, often disabling neurological disease characterised by recurrent attacks of headache pain that are typically unilateral and throbbing.[3] Menstrual migraine attacks are typically more severe, last longer, and are more likely to recur the next day than non-menstrual attacks. Menstrual migraines can be triggered by a drop in oestrogen levels, such as naturally occurs around menstruation. Oestrogen 'withdrawal' also triggers migraine in other situations, such as the pill-free interval of combined oral contraceptives. Menstrual migraines are likely to occur in the two days leading up to a period and the first three days of a period.[10] The main symptoms of a migraine attack are throbbing headache, nausea, vomiting, being very sensitive to light and sounds.[11] Due to a lack of awareness of the condition, menstrual migraine is often underdiagnosed. While people with MM may only experience 2–3 migraine days a month, these attacks may be severe, resulting in a high burden of disease.[3]

Women are two to three times more likely than men to be affected by migraine, with research estimating that approximately two thirds of females with migraine may experience menstrual migraine.[3] Menstrual migraine without aura is estimated to affect 4–8% of all women and 18–25% of female migraineurs, while the prevalence of menstrual migraine with aura has been estimated to affect 1.7–8.1% of female migraineurs.[12] About 50 to 60 per cent of women notice a link between their migraine and periods.[10] In England, 2024-25, there were 3,322 finished consultant episodes (FCE) for other migraine (ICD 10 code G43.8), with 2,767 hospital admissions which resulted in 2,682 FCE bed days and 1,502-day cases. there were also 2,333 finished consultant episodes (FCE) for migraine without aura (ICD 10 code G43.0), with 2,200 hospital admissions which resulted in 834 FCE bed days and 1,663-day cases. There were 8,033 finished consultant episodes (FCE) for migraine with aura (ICD 10 code G43.1), with 6,340 hospital admissions which resulted in 7,295 FCE bed days and 1,845-day cases.[13] The exact population for this indication cannot be gathered from the current literature and data.

Recommended Treatment Options

The National Institute of Health Care and Excellence (NICE) recommends the following: for predictable menstrual-related migraine that does not respond adequately to standard acute treatment, consider treatment with frovatriptan (2.5 mg twice a day) or zolmitriptan (2.5 mg, twice or three times a day) on the days migraine is expected.[14]

Clinical Trial Information

Trial	**ATO MM**, NCT06806293, CTIS 2024-512946-41-00; A Phase 3, multicentre, randomised, double-blind, placebo-controlled study with an open-label extension to evaluate the efficacy, safety, and tolerability of atogepant for the preventive treatment of menstrual migraine. **Phase III**-Recruiting **Location(s):** 7 EU countries, UK and other countries **Primary completion date**- February 2027
Trial Design	Randomised, parallel assignment, placebo-controlled, triple-blinded.
Population	N=430 (estimated); female subjects with menstrual migraine; aged 18 years and older

Copyright © National Institute for Health and Care Research Innovation Observatory, The University of Newcastle upon Tyne.

Intervention(s)	Atogepant oral tablet
Comparator(s)	Matched placebo
Outcome(s)	Primary outcome: change in Number of Migraine Days Occurring During the Perimenstrual Period See trial record for full list of other outcomes
Results (efficacy)	-
Results (safety)	-

Estimated Cost

Atogepant is already marketed in the UK for prophylaxis of migraine in adults who have at least 4 migraine days per month.[15] Atogepant is also marketed in the UK for the acute treatment of migraine with or without aura in adults.[9] The NHS indicative price for 28 tablets of 10mg and 60mg is £182.16.[16]

Relevant Guidance

NICE Guidance

- NICE quality standard. Headaches in over 12s (QS42). August 2013.

NHS England (Policy/Commissioning) Guidance

- NHS England. NHS Standard Contract for Specialised Pain. D08/S/a.
- NHS England. NHS Standard Contract for Neurosurgery. D03/S/a.
- NHS England. Clinical Commissioning Policy: Occipital Nerve Stimulation for Adults with Intractable Chronic Migraines and Medically Refractory Chronic Cluster Headaches. D08/P/c. July 2015.

Other Guidance

- British Association for the Study of Headache. National Headache Management System for Adults. 2026.[17]
- Association of Migraine Disorders. Clinical Recommendations for Managing Menstrual Migraine.2025.[18]
- Scottish Intercollegiate Guidelines Network. Pharmacological management of migraine. 2023.[19]

Additional Information

References

Copyright © National Institute for Health and Care Research Innovation Observatory, The University of Newcastle upon Tyne.

1 Clinicaltrials.gov. *A Phase 3, Multicenter, Randomized, Double-Blind, Placebo-Controlled Study With an Open-Label Extension to Evaluate the Efficacy, Safety, and Tolerability of Atogepant for the Preventive Treatment of Menstrual Migraine*. 2025. Available from: https://clinicaltrials.gov/study/NCT06806293 [Accessed 19 March 2026].

2 European Medical Compendium (emc). *AQUIPTA 60 mg tablets*. 2025. Available from: https://www.medicines.org.uk/emc/product/15049/smpc [Accessed 19 March 2026].

3 Terwindt G, Ailani J, Cirillo J, Abraham L, Jenkins A, Saccone P, et al. Underdiagnosis and impact of menstrual migraine in real-world clinical practice: A real-world survey. *Headache*. 2025;65(8):1413-27. Available from: https://doi.org/10.1111/head.14996.

4 Chowdhury S, Dave T. Novel Oral CGRP Receptor Antagonist Atogepant in the Prevention of Migraine. *Discoveries (Craiova)*. 2023;11(2):e167. Available from: https://doi.org/10.15190/d.2023.6.

5 Labastida-Ramírez A, Caronna E, Gollion C, Stanyer E, Dapkute A, Braniste D, et al. Mode and site of action of therapies targeting CGRP signaling. *Journal of Headache and Pain*. 2023;24(1):125. Available from: https://doi.org/10.1186/s10194-023-01644-8.

6 Edvinsson L. Role of CGRP in Migraine. 2019:121-30. Available from: https://doi.org/10.1007/164_2018_201.

7 Silvestro M, Orologio I, Bonavita S, Scotto di Clemente F, Fasano C, Tessitore A, et al. Effectiveness and Safety of CGRP-mAbs in Menstrual-Related Migraine: A Real-World Experience. *Pain and Therapy*. 2021;10(2):1203-14. Available from: https://doi.org/10.1007/s40122-021-00273-w.

8 Ailani J, Lipton RB, Goadsby PJ, Guo H, Miceli R, Severt L, et al. Atogepant for the Preventive Treatment of Migraine. *New England Journal of Medicine*. 2021;385(8):695-706. Available from: https://doi.org/doi:10.1056/NEJMoa2035908.

9 Electronic Medicines Compendium. *AQUIPTA 60 mg tablets*. 2026. Available from: https://www.medicines.org.uk/emc/product/15049/smpc [Accessed 06 May 2026].

10 National Migraine Centre. *Menstrual migraine; A National Migraine Centre factsheet*. 2026. Available from: https://www.nationalmigrainecentre.org.uk/understanding-migraine/factsheets-and-resources/menstrual-migraine/ [Accessed 26 March 2026].

11 NHS. *Migraine*. 2026. Available from: https://www.nhs.uk/conditions/migraine/ [Accessed 26 March 2026].

12 National Institute for Health and Care Excellence (NICE). *Migraine: How common is it?* Available from: https://cks.nice.org.uk/topics/migraine/background-information/prevalence/ [Accessed 10 April 2026].

13 NHS Digital. *Hospital Admitted Patient Care Activity, 2024-25*. 2025. Available from: https://digital.nhs.uk/data-and-information/publications/statistical/hospital-admitted-patient-care-activity/2024-25 [Accessed 26 March 2026].

14 National Institute for Health and Care Excellence (NICE). *Headaches in over 12s: diagnosis and management; Clinical guideline:CG150*. Available from: https://www.nice.org.uk/guidance/cg150/chapter/Recommendations [Accessed 10 April 2026].

15 Electronic Medicines Compendium. *AQUIPTA 10 mg tablets*. 2025. Available from: https://www.medicines.org.uk/emc/product/15048/smpc [Accessed 10 April 2026].

16 National Institute for Health and Care Excellence (NICE). *Atogepant; Medicinal forms*. Available from: https://bnf.nice.org.uk/drugs/atogepant/medicinal-forms/.

17 British Association for the Study of Headache. *Migraine; Management*. Available from: https://bash.org.uk/2-1-3-migraine-management/ [Accessed 19 March 2026].

18 Association of Migraine Disorders. *Clinical Recommendations for Managing Menstrual Migraine*. Available from: https://www.migrainedisorders.org/clinical-recommendations-for-managing-menstrual-migraine/ [Accessed 19 March 2026].

Copyright © National Institute for Health and Care Research Innovation Observatory, The University of Newcastle upon Tyne.

19 Scottish Intercollegiate Guidelines Network. *Pharmacological management of migraine*. Available from: https://www.sign.ac.uk/sign-155-migraine [Accessed 19 March 2026].

NB: This briefing presents independent research funded by the National Institute for Health and Care Research (NIHR). The views expressed are those of the author and not necessarily those of the NHS, the NIHR or the Department of Health.

Copyright © National Institute for Health and Care Research Innovation Observatory, The University of Newcastle upon Tyne.