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NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Health Technology Evaluation

Atogepant for treating migraine ID6615

Draft scope

Draft remit/evaluation objective

To appraise the clinical and cost effectiveness of atogepant within its marketing authorisation for treating migraine

Background

Migraine is primarily a headache disorder manifesting as recurring attacks usually lasting between 2 and 72 hours involving throbbing head pain of moderate to severe intensity. It is often accompanied by nausea, sometimes vomiting, sensitivity to light, sensitivity to sounds, and/or other sensory stimuli. Migraine can have significant impacts on quality of life and ability to carry out normal activities. Some people can have warning symptoms called an aura, before the start of a headache.

In 2025, a study based in 5 European countries estimated a prevalence of 10.4% for diagnosed migraines in the UK.[1] It is estimated that there are 190,000 migraine attacks experienced every day in England. Prevalence has been reported to be 5-25% in women and 2-10% in men.[2]

Treatments for acute migraine attacks include analgesics, triptans and anti-emetics. NICE clinical guideline 150 and the NICE pathway on the management of migraine (with or without aura) recommend an oral triptan with either a nonsteroidal anti-inflammatory drug (NSAID) or paracetamol, taking into account patient preferences, comorbidities and the risk of adverse events. For people who prefer to take only one drug, monotherapy with an oral triptan, NSAID, high dose aspirin or paracetamol should be considered. Anti-emetics should be considered in addition to other acute migraine treatment even in the absence of nausea and vomiting.

NICE technology appraisal 919 recommends rimegepant as an option for the acute treatment of migraine with or without aura in adults, only if for previous migraines:

- at least 2 triptans were tried and they did not work well enough or
- triptans were contraindicated or not tolerated, and NSAIDs and paracetamol were tried but did not work well enough.

The technology

Atogepant (Aquipta, AbbVie) does not currently have a marketing authorisation in the UK for treatment of migraine. It has been studied in randomised placebo-controlled clinical trials as a treatment for migraine in adults who have a history of migraine onset before 50 years.

Atogepant has a marketing authorisation in the UK for the prophylaxis of migraine in adults who have at least 4 migraine days per month.

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Intervention(s)	Atogepant
Population(s)	Adults with migraine (with or without aura)
Subgroups	If the evidence allows, the following subgroups will be considered: • people with chronic or episodic migraine • subgroups defined by the number of previous preventive treatments • subgroups defined by the frequency of episodic migraine
Comparators	• Rimegepant • Paracetamol, with or without an anti-emetic • An NSAID (such as aspirin, ibuprofen, diclofenac or naproxen), with or without an anti-emetic • An oral or non-oral triptan (such as sumatriptan, zolmitriptan, rizatriptan, almotriptan or eletriptan), with or without an anti-emetic • Paracetamol with an oral or non-oral triptan, with or without an anti-emetic • An NSAID with a triptan, with or without an anti-emetic • Best supportive care
Outcomes	The outcome measures to be considered include: • reduction in headache pain (including freedom from pain) • speed of onset • freedom from most bothersome symptom • reduction in nausea and vomiting • reduction in hypersensitivity (e.g. light, sound, smell) • regain of normal functioning • prevention of recurrence • use of rescue medication • adverse effects of treatment • health-related quality of life.

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Economic analysis	The reference case stipulates that the cost effectiveness of treatments should be expressed in terms of incremental cost per quality-adjusted life year. The reference case stipulates that the time horizon for estimating clinical and cost effectiveness should be sufficiently long to reflect any differences in costs or outcomes between the technologies being compared. Costs will be considered from an NHS and Personal Social Services perspective. The availability and cost of biosimilar and generic products should be taken into account.
Other considerations	Guidance will only be issued in accordance with the marketing authorisation. Where the wording of the therapeutic indication does not include specific treatment combinations, guidance will be issued only in the context of the evidence that has underpinned the marketing authorisation granted by the regulator.
Related NICE recommendations	**Related Technology Appraisals:** 'Rimegepant for treating migraine' (2023). NICE technology appraisal TA919. 'Atogepant for preventing migraine' (2024) NICE technology appraisal TA973 **Related Guidelines:** 'Headaches in over 12s: diagnosis and management' (2012). NICE guideline CG150. Updated 2015. Reviewed 2016. **Related Interventional Procedures:** 'Transcranial magnetic stimulation for treating and preventing migraine' (2014). NICE interventional procedures guidance 477. 'Transcutaneous stimulation of the cervical branch of the vagus nerve for cluster headache and migraine' (2016). NICE interventional procedures guidance 552. 'Transcutaneous electrical stimulation of the supraorbital nerve for treating and preventing migraine' (2022). NICE interventional procedures guidance 740 **Related Quality Standards:** 'Headaches in over 12s' (2013). NICE quality standard 42.

Questions for consultation

Where do you consider atogepant will fit into the existing care pathway for treating migraines?

What treatments would you consider to be appropriate comparators to atogepant?

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Please select from the following, will atogepant be:
A. Prescribed in primary care with routine follow-up in primary care
B. Prescribed in secondary care with routine follow-up in primary care
C. Prescribed in secondary care with routine follow-up in secondary care
D. Other (please give details):
For comparators and subsequent treatments, please detail if the setting for prescribing and routine follow-up differs from the intervention.

Would atogepant be a candidate for managed access?

Do you consider that the use of atogepant can result in any potential substantial health-related benefits that are unlikely to be included in the QALY calculation?

Please identify the nature of the data which you understand to be available to enable the committee to take account of these benefits.

Please indicate if any of the treatments in the scope are used in NHS practice differently than advised in their Summary of Product Characteristics. For example, if the dose or dosing schedule for a treatment is different in clinical practice. If so, please indicate the reasons for different usage of the treatment(s) in NHS practice. If stakeholders consider this a relevant issue, please provide references for data on the efficacy of any treatments in the pathway used differently than advised in the Summary of Product Characteristics.

NICE is committed to promoting equality of opportunity, eliminating unlawful discrimination and fostering good relations between people with particular protected characteristics and others. Please let us know if you think that the proposed remit and scope may need changing in order to meet these aims. In particular, please tell us if the proposed remit and scope:

- could exclude from full consideration any people protected by the equality legislation who fall within the patient population for which atogepant will be licensed;

- could lead to recommendations that have a different impact on people protected by the equality legislation than on the wider population, e.g. by making it more difficult in practice for a specific group to access the technology;

- could have any adverse impact on people with a particular disability or disabilities.

Please tell us what evidence should be obtained to enable the committee to identify and consider such impacts.

NICE intends to evaluate this technology through its Single Technology Appraisal process. (Information on NICE's health technology evaluation processes is available at https://www.nice.org.uk/about/what-we-do/our-programmes/nice-guidance/nice-technology-appraisal-guidance/changes-to-health-technology-evaluation).

References

1. Coppola, G., et al. (2025) The epidemiology and unmet need of migraine in five European countries: results from the national health and wellness survey. BMC Public Health 25, 254.

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2. Steiner TJ et al. The prevalence and disability burden of adult migraine in England and their relationships to age, gender and ethnicity. Cephalalgia. 2003;23(7):519-527.