NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Health Technology Evaluation

Atogepant for preventing migraine

Final scope

Remit/evaluation objective

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

Background

A migraine is primarily a headache disorder which manifests as a throbbing head pain. It may be accompanied by nausea, vomiting, and sensitivity to light, sound or other sensory stimuli. Migraine attacks usually last from 4 to 72 hours. Some people experience disturbances known as aura, which precede the headache and other symptoms, but the most common type of migraine is without aura. Aura can be visual in nature, or can involve numbness, tingling sensations and loss of balance. The exact cause of migraines is unknown but is thought to be linked to changes in brain activity which temporarily affects nerve signals, chemicals and blood vessels in the brain. Factors that can trigger these changes include stress, changes in sleep pattern, overtiredness, menstruation or environmental triggers such as bright lights or specific medicines.

Migraine is on a continuum, and it is possible for people to move between episodic and chronic migraine:

- Episodic migraine is defined as the occurrence of headaches on less than 15 days per month.

- Chronic migraine is defined by the International Classification of Headache Disorders 3rd edition (ICHD-3)[1]. It is described as headache occurring on 15 or more days a month for more than 3 months, which, on at least 8 days a month, has the features of migraine headache.

Around 10 million people aged 15 to 69 in the UK experience migraines.[1] Migraine is more common in women (about 1 in 5) than men (about 1 in 15).[2]

There are 3 broad approaches to managing migraine: lifestyle and trigger management, acute treatments and preventive (prophylactic) treatments. Preventive treatment of migraines can take many forms including nutritional supplements, lifestyle alterations such as increased exercise and avoidance of migraine triggers. It can also include medications, which are generally considered for people depending on their disease burden and frequency of attacks.

NICE clinical guideline 150 recommends offering topiramate or propranolol, and considering amitriptyline, for the prophylactic treatment of migraine according to the person's preference, comorbidities and risk of adverse events. The following medications have been recommended following NICE technology appraisal guidance:

- TA260 botulinum toxin type A for the prevention of headaches in adults with chronic migraine (only if the migraine has not responded to at least three prior pharmacological prophylaxis therapies)

- TA659 galcanezumab for preventing migraine (only if adults have 4 or more migraine days a month and at least 3 preventive drug treatments have failed)

- TA682 erenumab for preventing migraine (only if adults have 4 or more migraine days a month, at least 3 preventive drug treatments have failed and the 140mg dose of erenumab is used)

- TA764 fremanezumab for preventing migraine (only if adults have 4 or more migraine days a month, at least 3 preventive drug treatments have failed)

The technology

Atogepant (brand name unknown, AbbVie) does not currently have a marketing authorisation in the UK for migraine. It has been studied in clinical trials which compare it with placebo in adults with at least a 1-year history of episodic or chronic migraine. Some of the trials included people who had no previous prophylactic treatment while others included those who had had failed prophylactic medication from 2 to 4 medication classes.

Intervention(s)	Atogepant
Population(s)	Adults with migraine who have 4 or more migraine days a month, in whom at least 3 preventive drug treatments have failed
Subgroups	If the evidence allows, the following subgroups will be considered: • Those with either chronic or episodic migraine • Subgroups defined by the frequency of episodic migraine (in those with episodic migraine) • Subgroups defined by the number of previous prophylactic treatments
Comparators	• Botulinum toxin type A (for chronic migraine only) • Galcanezumab • Erenumab • Fremanezumab • Eptinezumab (subject to NICE evaluation) • Rimegepant (subject to NICE evaluation)

Outcomes	The outcome measures to be considered include: • change in frequency of headache days per month • change in frequency of migraine days per month • change in severity of headaches and migraines • change in number of cumulative hours of headache or migraine on headache or migraine days • changes in acute pharmacological medication used • adverse effects of treatment • health-related quality of life.
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. If the technology is likely to provide similar or greater health benefits at a similar or lower cost than technologies recommended in published NICE technology appraisal guidance for the same indication, a cost-comparison may be carried out. 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 of any commercial arrangements for the intervention, comparator and subsequent treatment technologies will be taken into account 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** Fremanezumab for preventing migraine (2022) NICE technology appraisal guidance 764 Erenumab for preventing migraine (2021) NICE technology appraisal guidance 682

	Galcanezumab for preventing migraine (2020) NICE technology appraisal 659 Botulinum toxin type A for the prevention of headaches in adults with chronic migraine (2012) NICE technology appraisal guidance 260 **Related appraisals in development** Eptinezumab for preventing migraine [ID3803] Publication expected May 2023 Rimegepant for treating or preventing migraine [ID1539] Publication expected March 2023 **Related interventional procedures** Transcutaneous electrical stimulation of the supraorbital nerve for treating and preventing migraine (2016) NICE interventional procedure guidance 559 Transcutaneous stimulation of the cervical branch of the vagus nerve for cluster headache and migraine (2016) NICE interventional procedure guidance 552 Transcranial magnetic stimulation for treating and preventing migraine (2014) NICE interventional procedure guidance 477
Related National Policy	NHS England (July 2015) Occipital Nerve Stimulation for Adults with Intractable Chronic Migraines and Medically Refractory Chronic Cluster Headaches Clinical Commissioning Policy Reference D08/P/c The NHS Long Term Plan, 2019. NHS Long Term Plan

References

1. NHS England (2020) Improved NHS migraine care to save thousands of hospital stays. NHS England » Improved NHS migraine care to save thousands of hospital stays Accessed 01/08/2022

2. NHS (2019) Conditions: Migraine overview Migraine - NHS (www.nhs.uk) accessed 01/08/2022