NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Single Technology Appraisal

Erenumab for preventing migraine [ID1188]

Final scope

Remit/appraisal objective

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

Background

Migraine is primarily a headache disorder manifesting as recurring attacks usually lasting for 4–72 hours involving throbbing head pain of moderate to severe intensity. It is often accompanied by nausea, sometimes vomiting, sensitivity to light, sensitivity to sound, and/or other sensory stimuli. Migraine can have a significant impact 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. Factors that can trigger attacks in people susceptible to migraines include stress, change in sleep pattern, overtiredness, menstruation, consumption of caffeine or alcohol, climatic conditions and use of visual display units.

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 Headache Society as the occurrence of headaches on 15 days or more per month for at least 3 months where the attacks fulfil criteria for pain and associated symptoms of migraine without aura on at least 8 days per month for at least 3 months, where there is no medication overuse, and where the headaches are not attributable to another causative disorder. A person must previously have had at least 5 attacks fulfilling the International Headache Society's criteria for migraine with or without aura.

It is estimated that there are 190,000 migraine attacks experienced every day in England.[1] Prevalence has been reported to be 5–25% in women and 2–10% in men.[1]

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, and prophylactic migraine medications. It can also include medications, which are generally considered for people who have at

least 2 attacks a month, whose attacks are increasing in frequency, whose attacks cause significant disability despite abortive treatment, or who cannot take abortive treatment for migraine 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.

NICE technology appraisal guidance 260 recommends botulinum toxin type A for the prophylaxis of headaches in adults with chronic migraine that has not responded to at least 3 prior pharmacological prophylaxis therapies and whose condition is appropriately managed for medication overuse.

The technology

Erenumab (Aimovig, Novartis) is a fully human monoclonal antibody that inhibits the action of calcitonin gene-related peptide (CGRP) which is believed to transmit signals that can cause severe pain. Erenumab is administered by subcutaneous injection.

Erenumab does not currently have a marketing authorisation in the UK for preventing migraine. It has been studied in clinical trials, compared with placebo, in adults with episodic or chronic migraine. The trials included people who had no previous prophylactic treatment and people who had no therapeutic response with up to 4 previous prophylactic treatments.

Intervention	Erenumab.
Population	People with migraine.
Comparators	Established clinical management for migraine prophylaxis without erenumab, including Botulinum toxin type A for chronic migraine that has not responded to at least 3 prior pharmacological prophylaxis therapies.
Outcomes	The outcome measures to be considered include: • frequency of headache days per month • frequency of migraine days per month • severity of headaches and migraines • number of cumulative hours of headache or migraine on headache or migraine days • reduction in acute pharmacological medication • 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. 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.
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. If the evidence allows, the following subgroups will be considered: • people with chronic or episodic migraine • subgroups defined by the number of previous prophylactic treatments • subgroups defined by the frequency of episodic migraine.
Related NICE recommendations and NICE Pathways	Related Technology Appraisals: 'Botulinum toxin type A for the prevention of headaches in adults with chronic migraine' (2012). NICE Technology Appraisal 260. Transferred to the static guidance list. Related Guidelines: 'Headaches in over 12s: diagnosis and management' (2012). NICE guideline CG150. Updated 2015. Next review date 2021. Related Interventional Procedures: 'Transcranial magnetic stimulation for treating and preventing migraine' (2014). NICE interventional procedures guidance 477. Review date TBC. 'Occipital nerve stimulation for intractable chronic migraine' (2013). NICE interventional procedures guidance 452. Review date TBC. 'Percutaneous closure of patent foramen ovale for recurrent migraine' (2010). NICE interventional procedures guidance 370. Review date TBC.

	Related Quality Standards: 'Headaches in over 12s' (2013). NICE quality standard 42. Related NICE Pathways: Headaches (2016) NICE pathway https://pathways.nice.org.uk/pathways/headaches
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 Department of Health (2016) NHS outcomes framework 2016 to 2017: Domain 2

References

1. 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.