NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Proposed Health Technology Appraisal

Erenumab for preventing migraine

Draft scope (pre-referral)

Draft 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. 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, consumption of caffeine or alcohol, climatic conditions and use of visual display units.

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. To fulfil the criteria for chronic migraine, a person must previously have had at least five attacks fulfilling the International Headache Society's criteria for migraine without aura. Despite these criteria, in clinical practice, there is a lack of consensus regarding the definition of chronic migraine.

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 chronic migraine: lifestyle and trigger management, acute treatments and preventive (or prophylactic) treatments. Preventative treatment of migraines can be an important component of chronic migraine management. It can take many forms including nutritional supplements, lifestyle alterations such as increased exercise and avoidance of migraine triggers, and prophylactic migraine medications. Prophylactic chronic migraine medications 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. Prophylactic migraine medications include beta-blockers, calcium

channel-blockers, the antidepressant amitriptyline, anti-seizure medication, and serotoninergic modulators.

NICE technology appraisal guidance 260 recommends botulinum toxin type A as an option 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 (brand name unknown, Novartis) is a fully human monoclonal antibody that inhibits the activity of calcitonin gene-related peptide (CGRP) which plays a key role in migraine pathophysiology. Erenumab also inhibits the CGRP receptor that 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 a one-year history of episodic migraine. The trials excluded people who had no therapeutic response with more than 2 prophylactic treatments.

Intervention(s)	Erenumab
Population(s)	Adults with a history of episodic migraine.
Comparators	Established clinical management without erenumab.
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.
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: Clinical Guideline No 150, September 2011 'Headaches in over 12's': diagnosis and management. Review date TBC. Related Interventional Procedures: Interventional Procedure Guidance No.477, January 2014, 'Transcranial magnetic stimulation for treating and preventing migraine'. Review date TBC. Interventional Procedure Guidance No4 52., April 2013, Occipital nerve stimulation for intractable chronic migraine'. Review date TBC. Interventional Procedure Guidance No. 370, December 2010, 'Percutaneous closure of patent foramen ovale for recurrent migraine'. Review date TBC. Related Quality Standards: 'Headaches in over 12s' (2013). NICE quality standard 42. Related NICE Pathways: Headaches (2016) NICE pathway http://pathways.nice.org.uk/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 National Service Framework Long Term Conditions (including neurological) Department of Health (2016) NHS outcomes framework 2016 to 2017

Questions for consultation

Which treatments are considered to be established clinical practice in the NHS for treating migraine?
Are there any treatments that would be displaced if erenumab was recommended?

Are the outcomes listed appropriate?

Are there any subgroups of people in whom erenumab is expected to be more clinically effective and cost effective or other groups that should be examined separately?

Where do you consider erenumab will fit into the existing NICE pathway?

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 erenumab 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.

Do you consider erenumab to be innovative in its potential to make a significant and substantial impact on health-related benefits and how it might

improve the way that current need is met (is this a 'step-change' in the management of the condition)?

Do you consider that the use of erenumab can result in any potential significant and 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 Appraisal Committee to take account of these benefits.

To help NICE prioritise topics for additional adoption support, do you consider that there will be any barriers to adoption of this technology into practice? If yes, please describe briefly.

NICE intends to appraise this technology through its Single Technology Appraisal (STA) Process. We welcome comments on the appropriateness of appraising this topic through this process. (Information on the Institute's Technology Appraisal processes is available at http://www.nice.org.uk/article/pmg19/chapter/1-Introduction).

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.