NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Health Technology Appraisal

Fremanezumab for preventing migraine

Final scope

Remit/appraisal objective

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

Background

Migraine is primarily a headache disorder manifesting as recurring attacks usually lasting between 4 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 sound, 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. 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 Classification of Headache Disorders 3rd edition (ICHD-3)[1]. It is described as headache occurring on 15 or more days a month, which, on at least 8 days a month, has the features of migraine headache.

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

There are 3 broad approaches to managing migraine: lifestyle and trigger management, acute treatments and preventive 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 preventing migraine according to the person's preference, comorbidities and risk of adverse events.

NICE technology appraisal guidance 260 recommends botulinum toxin type A for preventing 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

Fremanezumab (brand name unknown, Teva Pharmaceuticals) is a fully humanised monoclonal antibody that inhibits the action of calcitonin gene-related peptide (CGRP) which is believed to transmit signals that can cause severe pain. Fremanezumab is administered by subcutaneous injection.

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

Intervention(s)	Fremanezumab
Population(s)	Adults with chronic or episodic migraine
Comparators	Established clinical management for migraine prevention without fremanezumab, including: • Oral preventive treatments (such as topiramate, propranolol, amitriptyline) • Botulinum toxin type A • Erenumab (subject to ongoing NICE appraisal) • Best supportive care
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. If the technology is likely to provide similar or greater health benefits at 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.
Other considerations	If the evidence allows, the following subgroups will be considered: • people with chronic or episodic migraine • subgroups defined by the number of previous preventative treatments • subgroups defined by the frequency of episodic migraine. 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. On static list. Appraisals in development: Erenumab for preventing migraine [ID1188]. Publication date to be confirmed. Related Guidelines: Headaches in over 12s: diagnosis and management (2012). NICE guideline CG150.

	Related Interventional Procedures: Transcutaneous stimulation of the cervical branch of the vagus nerve for cluster headache and migraine (2016) NICE interventional procedures guidance 552. Implantation of a sphenopalatine ganglion stimulation device for chronic cluster headache (2015) NICE interventional procedures guidance 527. Transcranial magnetic stimulation for treating and preventing migraine (2014) NICE interventional procedures guidance 477. Occipital nerve stimulation for intractable chronic migraine (2013) NICE interventional procedures guidance 452. Percutaneous closure of patent foramen ovale for recurrent migraine (2010) NICE interventional procedures guidance 370. Related Quality Standards: Headaches in over 12s (2013). NICE quality standard 42. Related NICE Pathways: Headaches (2017) NICE Pathway.
Related National Policy	NHS England (2015) Occipital Nerve Stimulation for Adults with Intractable Chronic Migraines and Medically Refractory Chronic Cluster Headaches Clinical Commissioning Policy Reference D08/P/c NHS England (2013) Specialised services for pain management (Adult). Reference D08/S/a. Department of Health, NHS Outcomes Framework 2016-2017 (published 2016): Domain 2.

References

1. The International Headache Society. International Classification of Headache Disorders 3rd edition (ICHD-3). Accessed October 2018.

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.