NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Health Technology Appraisal

Eptinezumab for preventing migraine ID3803

Draft scope

Draft remit/appraisal objective

To appraise the clinical and cost effectiveness of eptinezumab 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 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. 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 (TA) guidance recommends the following treatments for preventing migraine in adults:

- TA682 recommends erenumab for preventing migraine in adults who experience 4 or more migraine days a month and at least 3 preventive drug treatments have failed.

- TA659 recommends galcanezumab for preventing migraine in adults who experience 4 or more migraine days a month and at least 3 preventive drug treatments have failed.

- TA631 recommends fremanezumab for preventing migraine in adults if the migraine is chronic and at least 3 preventive drug treatments have failed

- TA260 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

Eptinezumab (Vyepti, Lundbeck) is a humanised monoclonal antibody. It inhibits the action of calcitonin gene-related peptide (CGRP) which is believed to transmit signals that can cause severe pain. Eptinezumab is administered every 3 months by intravenous infusion.

Eptinezumab does not currently have a marketing authorisation in the UK for preventing migraine. It has been studied in clinical trials, either on its own or compared with placebo, in adults with at least a 1-year history of chronic or episodic migraine.

Intervention(s)	Eptinezumab
Population(s)	Adults with migraine
Comparators	• Oral preventive treatments (such as topiramate, propranolol, amitriptyline) • Erenumab (4 or more migraine days per month and after at least 3 preventive drug treatments have failed) • Galcanezumab (4 or more migraine days per month and after at least 3 preventive drug treatments have failed) • Fremanezumab (in chronic migraine and after at least 3 preventive drug treatments have failed) • Botulinum toxin type A (in chronic migraine that has not responded to at least 3 prior pharmacological prophylaxis therapies) • 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. 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 preventive 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**: Erenumab for preventing migraine (2021). NICE technology appraisal guidance 682. Review date 2024. Galcanezumab for preventing migraine (2020). NICE technology appraisal guidance 659. Review date 2023. Fremanezumab for preventing migraine (2020). NICE technology appraisal guidance 631. Review date 2023.

	Botulinum toxin type A for the prevention of headaches in adults with chronic migraine (2012). NICE technology appraisal guidance 260. Guidance on static list. **Appraisals in development (including suspended appraisals):** Rimegepant for treating or preventing migraine NICE technology appraisal guidance [ID1539]. Publication date to be confirmed. **Related Guidelines**: Headaches in over 12s: diagnosis and management (2012). Updated 2021. NICE clinical guideline 150. **Related Interventional Procedures**: Transcutaneous electrical stimulation of the supraorbital nerve for treating and preventing migraine (2016). NICE interventional procedures guidance 559. Transcutaneous stimulation of the cervical branch of the vagus nerve for cluster headache and migraine (2016). NICE interventional procedures guidance 552. 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 (2021) NICE pathway
Related National Policy	The NHS Long Term Plan, 2019. NHS Long Term Plan NHS England (2019) Headache and migraine toolkit NHS England (2018) NHS England Funding and Resource 2018/19: Supporting 'Next Steps for the NHS Five Year Forward View' Department of Health and Social Care, NHS Outcomes Framework 2016-2017: Domain 2. 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

Questions for consultation

Have all relevant comparators for eptinezumab been included in the scope?

Which treatments are considered to be established clinical practice in the NHS for preventing migraine?

How should best supportive care be defined?'

Are the outcomes listed appropriate?

Are the subgroups suggested in 'other considerations appropriate? Are there any other subgroups of people in whom eptinezumab is expected to be more clinically effective and cost effective or other groups that should be examined separately?

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

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 eptinezumab 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 eptinezumab 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 eptinezumab 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).

NICE has published an addendum to its guide to the methods of technology appraisal (available at https://www.nice.org.uk/Media/Default/About/what-we-do/NICE-guidance/NICE-technology-appraisals/methods-guide-addendum-cost-comparison.pdf), which states the methods to be used where a cost comparison case is made.

- Would it be appropriate to use the cost comparison methodology for this topic?
- Is the new technology likely to be similar in its clinical efficacy and resource use to any of the comparators?
- Is the primary outcome that was measured in the trial or used to drive the model for the comparator(s) still clinically relevant?
- Is there any substantial new evidence for the comparator technology/ies that has not been considered? Are there any important ongoing trials reporting in the next year?

References

1. The International Headache Society. International Classification of Headache Disorders 3rd edition (ICHD-3). Accessed November 2021.

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.