NICE National Institute for Health and Care Excellence

NICE guidance

Eptinezumab for preventing migraine

Technology appraisal guidance
Published: 1 March 2023

www.nice.org.uk/guidance/ta871

Your responsibility

The recommendations in this guidance represent the view of NICE, arrived at after careful consideration of the evidence available. When exercising their judgement, health professionals are expected to take this guidance fully into account, alongside the individual needs, preferences and values of their patients. The application of the recommendations in this guidance is at the discretion of health professionals and their individual patients and do not override the responsibility of healthcare professionals to make decisions appropriate to the circumstances of the individual patient, in consultation with the patient and/or their carer or guardian.

All problems (adverse events) related to a medicine or medical device used for treatment or in a procedure should be reported to the Medicines and Healthcare products Regulatory Agency using the Yellow Card Scheme.

Commissioners and/or providers have a responsibility to provide the funding required to enable the guidance to be applied when individual health professionals and their patients wish to use it, in accordance with the NHS Constitution. They should do so in light of their duties to have due regard to the need to eliminate unlawful discrimination, to advance equality of opportunity and to reduce health inequalities.

Commissioners and providers have a responsibility to promote an environmentally sustainable health and care system and should assess and reduce the environmental impact of implementing NICE recommendations wherever possible.

Contents

1 Recommendations

1.1 Eptinezumab is recommended as an option for preventing migraine in adults, only if:

- they have 4 or more migraine days a month
- at least 3 preventive medicines have not worked, or are not tolerated or are unsuitable because of safety concerns, and
- the company provides it according to the commercial arrangement.

1.2 Stop eptinezumab after 12 weeks of treatment if:

- in episodic migraine (fewer than 15 headache days a month), the frequency does not reduce by at least 50%
- in chronic migraine (15 headache days a month or more with at least 8 of those having features of migraine), the frequency does not reduce by at least 30%.

1.3 If people with the condition and their clinicians consider eptinezumab to be 1 of a range of suitable treatments (including erenumab, fremanezumab and galcanezumab), discuss the advantages and disadvantages of the available treatments. After that discussion, if more than 1 treatment is suitable, choose the least expensive. Take account of administration costs, dosage, price per dose and commercial arrangements.

1.4 These recommendations are not intended to affect treatment with eptinezumab that was started in the NHS before this guidance was published. People having treatment outside these recommendations may continue without change to the funding arrangements in place for them before this guidance was published, until they and their NHS clinician consider it appropriate to stop.

Why these recommendations were made

Treatments for preventing chronic or episodic migraines include erenumab, fremanezumab and galcanezumab when they have not responded to at least 3 oral preventive drug

treatments. These treatments are already recommended in NICE's technology appraisal guidance on erenumab, fremanezumab and galcanezumab. They are all administered as injections under the skin. Eptinezumab is another treatment option that works in a similar way but is administered as an infusion into a vein.

There are no clinical trials directly comparing eptinezumab with erenumab, fremanezumab or galcanezumab. An indirect comparison suggests that eptinezumab works as well as these treatments.

A cost comparison suggests that eptinezumab has similar costs and overall health benefits to erenumab, fremanezumab and galcanezumab. So, eptinezumab is recommended for preventing migraine if it is used in the same population as these treatments.

2 Information about eptinezumab

Marketing authorisation indication

2.1 Eptinezumab (VYEPTI, Lundbeck) is indicated for 'the prophylaxis of migraine in adults who have at least 4 migraine days per month'.

Dosage in the marketing authorisation

2.2 The dosage schedule is available in the summary of product characteristics for eptinezumab.

Price

2.3 The price of eptinezumab is £1,350 for a 100 mg per ml vial (excluding VAT; BNF online accessed January 2023).

2.4 The company has a commercial arrangement. This makes eptinezumab available to the NHS with a discount. The size of the discount is commercial in confidence. It is the company's responsibility to let relevant NHS organisations know details of the discount.

3 Discussion

The recommendations were made after consideration of the evidence submitted by Lundbeck, a review of this submission by the external assessment group (EAG) and submissions from stakeholders. See the committee papers for full details of the evidence.

The condition and current treatment

3.1 Patient and professional organisations, and patient experts described in their submissions how migraine has a significant effect on the quality of life for people with the condition, and their families and carers. They explained how migraine can negatively affect a person's work, family relationships, social life, and mental health and wellbeing. The submissions highlighted the high disease burden, particularly for people with frequent episodes of migraine, chronic migraine or other comorbidities. People with migraine first try a range of oral preventive drug treatments before considering more specialist treatment, such as botulinum toxin type A (for chronic migraine) or erenumab, fremanezumab or galcanezumab (for episodic or chronic migraine). Usual practice in the NHS is that there is an insufficient response to at least 3 oral preventive drug treatments before more specialist treatment is considered. Stakeholders commented that oral preventive drug treatments are often poorly tolerated and ineffective in preventing migraine. They also explained that access to specialist care and treatment can vary depending on where someone lives. It was agreed that there is a need for effective preventive treatments that can improve quality of life for people with migraine.

Comparators

3.2 Erenumab, fremanezumab and galcanezumab are calcitonin gene-related peptide (CGRP) inhibitors. They are recommended in NICE's technology appraisal guidance on erenumab, fremanezumab and galcanezumab for preventing chronic or episodic migraines after at least 3 oral preventive drug treatments have failed. These treatments are available as subcutaneous injections that can be self-administered at home. Erenumab is administered 4-weekly, galcanezumab

monthly, and fremanezumab monthly or 3-monthly. Eptinezumab is another CGRP inhibitor that works in a similar way, but it is administered by intravenous infusion every 12 weeks in hospital. Clinical opinion suggests that eptinezumab would therefore be reserved for people with severe migraine attacks or who are unable to use the CGRP inhibitors administered subcutaneously. This may include people who struggle to self-administer the injections, such as those with needle phobia. The EAG noted that the company's positioning of eptinezumab in its submission (people with episodic or chronic migraine who have had at least 3 oral preventive drug treatments) aligned with the positioning of the other CGRP inhibitors recommended by NICE. It was agreed that erenumab, fremanezumab and galcanezumab were all appropriate comparators.

Clinical effectiveness

3.3 The company did not identify any evidence directly comparing eptinezumab with the relevant comparators (see section 3.2). So, it did a network meta-analysis to indirectly compare eptinezumab with erenumab, fremanezumab and galcanezumab in people whose migraine had not responded to at least 3 preventive drug treatments. The company used data from randomised controlled trials that compared each of the treatments with placebo. The results of the network meta-analysis suggested that eptinezumab has similar clinical effectiveness to erenumab, fremanezumab and galcanezumab in reducing migraine frequency in people with chronic or episodic migraines. Clinical opinion also suggested that the treatments are similar. The EAG noted that there were some limitations associated with the company's network meta-analysis but that these had also been considered in NICE's technology appraisal guidance on erenumab, fremanezumab and galcanezumab. It was agreed that there was sufficient evidence of similar clinical efficacy for eptinezumab compared with erenumab, fremanezumab and galcanezumab.

Cost comparison

3.4 The company submission stated that 'eptinezumab is only available in a 100 mg vial; a 300 mg vial is not available, and the 300 mg dose is not being

commercialised in the UK'. When taking account of administration costs, dosage, price per dose and commercial arrangements for all treatments, the total cost associated with eptinezumab 100 mg every 12 weeks was similar to or lower than that with erenumab (140 mg 4-weekly), fremanezumab (225 mg monthly or 675 mg 3-monthly) or galcanezumab (120 mg monthly after a 240 mg initial loading dose). The exact results are confidential and cannot be reported here. It was agreed that, after people with the condition and their clinicians have discussed the advantages and disadvantages of the available treatments, if more than 1 treatment is suitable, it would be appropriate to choose the least expensive option. So, the decision was made to recommend eptinezumab for preventing migraine in line with the previous recommendations for erenumab, fremanezumab and galcanezumab.

Equality issues

3.5 Stakeholders raised several potential equality issues during the evaluation. This included that migraine is more common in women, particularly in those of childbearing age. But it was agreed that issues relating to differences in prevalence or incidence of a condition cannot be addressed in a technology evaluation. A stakeholder commented that appropriate treatments should be available for everyone including people who cannot self-administer available treatments because of a physical, cognitive or other disability. It was agreed that eptinezumab would likely improve access to specialist treatment for people with difficulty self-injecting the CGRP inhibitors administered subcutaneously. This is because it would be administered in a hospital setting intravenously. A stakeholder commented that there should be equality of access to treatment for people with migraine and that best supportive care should not be the default option because of where someone lives. The decision making took into account any obligations in relation to the Equality Act 2010 and that eptinezumab can only be recommended for use within its marketing authorisation. It was noted that issues about healthcare implementation could not be addressed in the evaluation. It was agreed that there were no equality issues relevant to the recommendations.

4 Implementation

4.1 Section 7 of the National Institute for Health and Care Excellence (Constitution and Functions) and the Health and Social Care Information Centre (Functions) Regulations 2013 requires integrated care boards, NHS England and, with respect to their public health functions, local authorities to comply with the recommendations in this evaluation within 3 months of its date of publication. Because eptinezumab has been recommended through the cost-comparison process, NHS England and commissioning groups have agreed to provide funding to implement this guidance 30 days after publication.

4.2 The Welsh ministers have issued directions to the NHS in Wales on implementing NICE technology appraisal guidance. When a NICE technology appraisal guidance recommends the use of a drug or treatment, or other technology, the NHS in Wales must usually provide funding and resources for it within 2 months of the first publication of the final draft guidance.

4.3 When NICE recommends a treatment 'as an option', the NHS must make sure it is available within the period set out in the paragraphs above. This means that, if a patient has migraine and the doctor responsible for their care thinks that eptinezumab is the right treatment, it should be available for use, in line with NICE's recommendations.

5 Evaluation committee members and NICE project team

Evaluation committee members

The highly specialised technologies evaluation committee is a standing advisory committee of NICE. This topic was considered by the vice chair of this committee.

Committee members are asked to declare any interests in the technology being evaluated. If it is considered there is a conflict of interest, the member is excluded from participating further in that evaluation.

Chair

Paul Arundel
Vice chair, highly specialised technologies evaluation committee

NICE project team

Each evaluation is assigned to a team consisting of 1 or more health technology analysts (who act as technical leads for the evaluation), a technical adviser and a project manager.

Anita Sangha
Technical lead

Caron Jones
Technical adviser

Kate Moore
Project manager

6 Update information

June 2025: We have made minor editorial changes to the wording in section 1.1 to align with the NICE guideline on headaches in over 12s: diagnosis and management. This does not affect the meaning or intent of the guidance.

ISBN: 978-1-4731-5037-9