Surrey Heartlands Integrated Care System Area Prescribing Committee (APC)
Integrated Care Partnerships (ICPs) (Surrey Downs, Guildford & Waverley, North West Surrey, East Surrey (as part of the CRESH system) & associated partner organisations.

Briefing Paper for Area Prescribing Committee on NICE Technology Appraisals: Local implementation

NICE TA Guidance	Galcanezumab for preventing migraine NICE Technology Appraisal guidance 659		
Available at	www.nice.org.uk/guidance/ta659		
Date of issue	18 November 2020	**Implementation deadline**	18 February 2021

Medicine details[1]	
Name, brand name and manufacturer	Galcanezuma (Emgality®). Eli Lilly and Company Limited
Mode of action	Galcanezumab is a recombinant humanised monoclonal antibody produced in Chinese Hamster Ovary cells
Licensed indication	Emgality® is indicated for the prophylaxis of migraine in adults who have at least 4 migraine days per month
Formulation	Emgality® 120 mg in 1 mL for injection in pre-filled pen
Usual dosage	The recommended dose is 120 mg galcanezumab injected subcutaneously once monthly, with a 240 mg loading dose as the initial dose. Patients should be instructed to inject a missed dose as soon as possible and then resume monthly dosing. The treatment benefit should be assessed within 3 months after initiation of treatment. Any further decision to continue treatment should be taken on an individual patient basis. Evaluation of the need to continue treatment is recommended regularly thereafter. *Elderly (≥ 65 years)* There is limited information in subjects aged ≥ 65 years. No dose adjustment is required as the pharmacokinetics of galcanezumab are not affected by age. *Renal impairment/hepatic impairment* No dose adjustment is required in patients with mild to moderate renal impairment or hepatic impairment. *Paediatric population* The safety and efficacy of galcanezumab in children aged 6 to 18 years have not yet been established. No data are available. There is no relevant use of galcanezumab in children below the age of 6 years for the prevention of migraine. This is the same recommended dose and schedule as the NICE TA. *This is the current dose considered by NICE as part of the NICE evaluation. Subsequent changes in the license following NICE publication will need to be considered by the Area*

	Prescribing Committee and will not be routinely funded by local commissioners.

Disease and potential patient group

Brief description of disease[2]

Migraine is a headache disorder with recurring attacks usually lasting between 4 and 72 hours. The patient expert explained the debilitating effect of migraine on their daily life with symptoms including fatigue, severe head pain, sensitivity to light, difficulty concentrating, nausea, stiff neck or back, feeling down, and sensitivity to sound.

These symptoms were noted to adversely affect someone's ability to do their usual activities, including work, and to negatively affect their family.

Chronic migraine is defined as 15 or more headache days a month with at least 8 of those having features of migraine.

Episodic migraine is defined as less than 15 headache days a month.

The clinical and patient experts explained that the severity and frequency can fluctuate over time and that recovery from a migraine can take a few days.

The committee concluded that migraine, particularly chronic migraine, is a debilitating condition that substantially affects both physical and psychological aspects of health-related quality of life.

Potential patient numbers[3]

Table1: Total number of people eligible for treatment with galcanezumab in England and per CCG.

Area	Population of people aged 18 and over	Episodic migraine	Chronic migraine	Total	Total resource impact
England	44,022,560	144,255	59,225	203,481	£45,309,440
Crawley	85,260	278	115	393	£87,592
Horsham and Mid-Sussex	186,990	612	252	863	£192,296
East Surrey	143,478	469	193	662	£147,512
Guildford and Waverly	165,668	542	223	765	£170,350
North West Surrey	270,500	885	364	1,249	£278,247
Surrey Downs	227,163	743	306	1,049	£233,643
Surrey Heath	76,072	248	102	351	£78,135

SUMMARY

Guidance[2]

1.1 Galcanezumab 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 drug treatments have failed and
- the company provides it according to the commercial arrangement.

1.2 Stop galcanezumab after 12 weeks of treatment if:

- in episodic migraine (less 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 This recommendation is not intended to affect treatment with galcanezumab that was started in the NHS before this guidance was published. People having treatment outside this recommendation 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.

Please note the following for clarification of the stopping criteria in chronic migraine, from the galcanezumab NICE TA i.e. whether stopping in chronic migraine is measured in a reduction in headache days or migraine days:

'It also concluded that a clinically meaningful response is a 30% reduction in migraine frequency for chronic migraine and a 50% reduction for episodic migraine'.

Cost implications*,[2]

Cost:
The list price of galcanezumab is £450.00 per 120-mg injection (excluding VAT; Monthly Index of Medical Specialities online, accessed October 2020).

The company has a commercial arrangement. This makes galcanezumab 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.

Annual or monthly cost per patient:
The recommended dose is 120 mg galcanezumab injected subcutaneously once monthly, with a 240 mg loading dose as the initial dose.

Annual cost: 13 doses @ £450 = £5,850

NHS resources of introducing galcanezumab may be higher for episodic migraine than for chronic migraine. This is because episodic migraine is more common than chronic migraine. However NICE concluded that galcanezumab is a cost-effective use of NHS resources for preventing episodic migraine after 3 oral preventive treatments have failed.

Availability of PAS and details (if appropriate):
The PAS price would be given to trusts which would reduce this cost.

The PAS price only applies to trusts and primary care headache clinics would not be able to prescribe and supply at this reduced price.

Availability of homecare service (if appropriate): Yes

Resource impact statement:
See Table 1 above.
**NICE funding requirements are based on Quality Adjusted Life Years (QALY) threshold. If there is evidence that the incremental cost rises above this threshold in the future, the APC may reconsider the commissioning status.*

Alternative treatments and cost per patient per year

Other NICE recommended products:[4,5]

NICE Botulinum toxin type A for the prevention of headaches in adults with chronic migraine. Technology appraisal guidance. Published: 27 June 2012

The current annual cost per patient is £1,419, as described below:

	Dose mg/vial	Frequency (weeks)	Price per vial	Annual cost

Drug costs	200	12	£238.8	£955

	Cost per appointment	Annual number of appointments	Annual cost
Administration costs	£116	4	£464

NICE Fremanezumab for preventing migraine. Technology appraisal guidance. Published: 3 June 2020

Fremanezumab and galcanezumab are both anti-calcitonin gene-related peptides (CGRPs) monoclonal antibody treatments:

Anti-CGRP	Annual cost
Fremanezumab (Ajovy®) – both monthly and quarterly dosing	£5,400
Galcanezumab (Emgality®) – monthly dosing	£5,850

The NICE TA for fremanezumab supports use in chronic migraine only. The NICE TA for galcanezumab supports use in both episodic and chronic migraine.

Please note that the NICE TA for galcanezumab states:
'The committee was aware of NICE's recently published technology appraisal guidance recommending fremanezumab for chronic migraine but noted that fremanezumab treatment was not routine clinical practice in the NHS at the time of its decision making, so it is not considered a comparator for galcanezumab'.

And also:

'The committee was not presented with any evidence to support subsequent treatment with other anti-CGRPs, if the initial clinically meaningful response to treatment with galcanezumab is subsequently lost.

The committee was aware although the scope included 2 medicines in this class as potential comparators, neither was established practice in the NHS at the time of the decision-making and therefore did not formally compare galcanezumab with them.

However, the committee heard from the clinical expert that there is no clinical evidence to support any difference in efficacy between the different anti-CGRP drugs.

The committee noted that treatment preferences are not outlined in the British Association for the Study of Headache's guidelines, and therefore considered it reasonable that the least expensive drug would be used unless an alternative was more suitable for the patient.

The committee concluded that treatment with another anti-CGRP drug, after failure of a previous anti-CGRP drug, is not supported by evidence and is not recommended.

Options not reviewed by NICE but used in standard practice:
Treatment options for preventing chronic or episodic migraine include beta-blockers, antidepressants and anticonvulsant drugs.

If chronic migraine does not respond to at least 3 preventive drug treatments, botulinum toxin type A, fremanezumab or best supportive care (treatment for the migraine symptoms) is offered. The NICE TAs for Botulinum toxin type A and fremanezumab do not support their use in episodic migraine.

Impact to patients

- An additional treatment option would be valued by patients, particularly those resistant to

current treatments.
- A new anti-CGRP treatment option for episodic migraine.
- Ease of use in comparison to botulinum toxin type A treatment (a 30-minute hospital appointment every 12 weeks for administration which consists of between 31 to 39 injections in the head and neck region).
- Limited to monthly dosing schedule compared to fremanezumab where a choice of monthly or quarterly dosing is available.
- Available under a homecare service so will be delivered directly to the patient.
- Patients in primary care headache services would need to be referred to the trust as a RED drug and in order to access the PAS price.
- Training may be required before a person can self-administer the treatment.
- Carers may have to help administer the sc injection if the patient has issues with dexterity or needle-phobia.

Impact to primary care prescribers

- This is a PbRe drug and is commissioned by CCGs for use in secondary care. There should be no prescribing in primary care.
- Primary care prescribers should be aware that their patient is receiving this medicine and ensure that this is recorded in the patient's notes in order to be alert to potential side-effects and interactions with other medicines prescribed in primary care. This will also ensure that GP records, which are accessed by other healthcare providers, are a true and accurate reflection of the patient's medication.
- Patients in primary care headache services would need to be referred to the trust as a RED drug and in order to access the PAS price.

Impact to secondary care

- An additional treatment option would be valued by clinicians.
- The initiation, administration and on-going treatment is managed by secondary care.
- Homecare arrangements will be managed by the trust.
- As it is available on homecare, patients will only require appointments for review and/or monitoring.
- Impact on clinic capacity as trusts are the providers of this service:
    - Potential reduction in the number of appointments for patients currently on botulinum toxin type A who require 12 weekly appointments for) and footfall within the trust.
- Potential increase in demand for appointments as new patients are identified, particularly for episodic migraine and those previously seen at tertiary centres.

Impact to CCGs

- The technology is commissioned by clinical commissioning groups (CCGs) and they are required to comply with the recommendations in the NICE TA within 3 months of its date of publication.
- Providers are NHS hospital trusts.
- Other novel biologic medicines for chronic migraine are expected.

Implementation

- Trusts to initiate homecare NICE TA implementation must be within 90 days of publication – 18th February 2021.
- This NICE TA provides another option alongside botulinum toxin type A and fremanezumab.
- Blueteq forms to be developed.
- Trusts to initiate homecare.
- Adapt the 'Secondary care pathway for prophylaxis of headaches in adults with chronic migraine: Fremanezumab NICE TA631 and Botulinum toxin type A NICE TA260 (specialist use only)' to include use of galcanezumab in both episodic and chronic migraine as per NICE TA.

Recommendation to PCN
PbRe: Yes **Recommended traffic light status (see attached guidelines):** RED **Additional comments:**

References:

1 Specification of Product Characteristics. Emgality 120 mg solution for injection in pre-filled pen. Available at: https://www.medicines.org.uk/emc/product/10478#gref Accessed 1.12.20.

2 Galcanezumab for preventing migraine. Technology appraisal guidance [TA659] Published date: 18 November 2020. Available at: https://www.nice.org.uk/guidance/TA659 Accessed 1.12.20

3 NICE Resource impact report: Galcanezumab for preventing migraine. Technology appraisal guidance [TA659] Published date: 18 November 2020. Available at: https://www.nice.org.uk/guidance/ta659/resources Accessed 2.12.20

4 Botulinum toxin type A for the prevention of headaches in adults with chronic migraine. Technology appraisal guidance [TA260]. Published date: 27 June 2012. NICE. Available at: https://www.nice.org.uk/guidance/ta260 Accessed 1.12.20

5 Ajovy (fremanezumab) 225 mg Pre-filled Syringe for Injection. eMC. Available at: https://www.medicines.org.uk/emc/product/10386/smpc Accessed 1.12.20

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Declaration of Interest: None

Date: 2.12.20

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Declaration of Interest:

Date