**National Institute for Health and Care Excellence**

**Single Technology Appraisal (STA)**

**Galcanezumab for preventing migraine ID1372**

**Response to consultee and commentator comments on the draft remit and draft scope (pre-referral)**

**Please note:** Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees.

**Comment 1: the draft remit**

| Section | Consultee/ Commentator | Comments [sic] | Action |
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| Appropriateness | Eli Lilly | We consider it appropriate to refer this topic to NICE for appraisal. | Comment noted. |
| | Novartis Pharmaceuticals UK Ltd | We consider the proposed appraisal appropriate. | Comment noted. |
| | Teva UK Limited | With other anti-CGRP therapies currently being appraised by NICE, it is appropriate for galcanezumab to also be assessed at this time. | Comment noted. |
| | Association of British Neurologists* | Yes: it is appropriate to refer this topic to NICE for appraisal. | Comment noted. |
| | The British Association for the Study of Headache | This is the third CGRP Monoclonal antibody to be available in the near future. Like Erenumab and Fremanezumab, it is appropriate for NICE to appraise Galcanezumab. | Comment noted. |
| | The Migraine Trust | Yes: Of the acute and preventative treatments available for migraine, many have been developed for other medical conditions. They have variable efficacy and are often associated with intolerable side effects. Even then, | Comment noted. |

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| | | medical comorbidities have also limited which medications may be used and the presence of medication overuse headache (MOH) can affect the utility of treatments.<br>A proportion of sufferers cannot use Triptans (a migraine specific treatment), due to contraindications and often have to resort to overuse of opiates which is not recommended for migraine. | |
| Wording | Eli Lilly | We consider the wording of the draft remit appropriate. | Comment noted. |
| | Teva UK Limited | The wording appears appropriate. | Comment noted. |
| | Association of British Neurologists | Yes | Comment noted. |
| | The British Association for the Study of Headache | Yes | Comment noted. |
| | The Migraine Trust | Yes | Comment noted. |
| Timing Issues | Eli Lilly | There is an ongoing trial (CONQUER; NCT03559257) assessing galcanezumab in adults with treatment-resistant migraine. We anticipate data from this trial will be available in [redacted]. This population reflects expected use in the NHS therefore we request this appraisal commences in [redacted] following the availability of this trial data. | Comments noted. NICE has scheduled this topic into its work programme. For further details, see the NICE website: https://www.nice.org.uk/guidance/proposed/gid-ta10454. |
| | Association of British Neurologists | The appraisal should be considered in a timely manner alongside NICE appraisals for other drugs in this class i.e. erenumab and fremanezumab. | Comments noted. NICE has scheduled this topic |

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| | | These treatments may be a step change in treatment for migraine with a lesser side effect profile, better adherence profile and equivalent or better efficacy data compared to current therapies for the commonest UK neurological disorder i.e. migraine | into its work programme. For further details, see the NICE website: https://www.nice.org.uk/guidance/proposed/gid-ta10454. No action required. |
| | The British Association for the Study of Headache | Considering NICE is already appraising the other two CGRP MAB, we suggest urgent appraisal for this product as all three will be available to choose from and it is important that we have NICE appraisal done timely. | Comments noted. NICE has scheduled this topic into its work programme. For further details, see the NICE website: https://www.nice.org.uk/guidance/proposed/gid-ta10454. No action required. |
| | The Migraine Trust | Migraine sufferers have an urgent need for targeted anti-migraine treatments that would reduce their suffering and disability by reducing the frequency and severity of attacks. The lack of adequate preventive treatments has contributed to the overuse of acute or over the counter medicines. Migraineurs will seek treatments to be able to function and this places them at risk of overusing acute treatments which doesn't address the problem but renders it more difficult to treat. | Comments noted. NICE has scheduled this topic into its work programme. For further details, see the NICE website: https://www.nice.org.uk/guidance/proposed/gid-ta10454. No action required. |

**Comment 2: the draft scope**

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| Background information | Association of British Neurologists | The use of prophylactic medication is considered not just on migraine frequency but on headache burden i.e. number of days of headache x severity of attacks. In the UK prophylaxis is generally considered if individuals experience at least 4 to 6 days per month of troublesome migraine or headache | Comment noted. This section of the scope aims to provide a brief overview of the background for the appraisal; additional details may be considered by the committee, if appropriate, at the time of the appraisal. No action required. |
| | The British Association for the Study of Headache | Migraine has more indirect costs to the economy than direct cost to the NHS. Lifestyle and trigger management is appropriate provided access to headache nurse support is easily available. The access to headache services is patchy and headache specialists cannot offer such services to their patients due to time constraints and waiting time to access the service.<br>Although NICE recommends topiramate, propranolol and amitriptyline for migraine prophylaxis, other drugs like candesartan, sodium valproate, venlafaxine may be offered based on individual needs and disease burden.<br>It is important to identify when prophylaxis should be offered and this should be based on the frequency, duration and intensity of individual attacks. | Comment noted. The NICE reference case stipulates that the perspective on costs should be that of the NHS and Personal Social Services. Please see sections 5.1.7 to 5.1.10 of the Guide to the methods of technology appraisal (2018) for more information.<br>Candesartan is covered in the scope under comparator treatments “oral preventative treatments” and may be |

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| | | | considered by the committee, if appropriate, at the time of the appraisal. No action required. |
| | The Migraine Trust | The information should include more recent updated literature that reflect the current state more closely. Examples include:<br>*Steiner et al (2018) Migraine is first cause of disability in under 50s. Journal of Headache and Pain 2018; 19(1): 17*<br>*www.who.int/news-room/fact-sheets/detail/headache-disorders*<br>*www.thelancet.com/journals/laneur/article/PIIS1474-4422(18)30360-0/fulltext* | Comment noted. The background section is only intended to give a brief overview of the condition, its epidemiology and the treatment pathway. No action required. |
| The technology/ intervention | Eli Lilly | Emgality (galcanezumab) received European Commission marketing authorisation in November 2018.<br>Therefore we recommend changing the description to 'Galcanezumab has a marketing authorisation in the UK for preventing migraine. Emgality is indicated for the prophylaxis of migraine in adults who have at least 4 migraine days per month'. | Comment noted. The technology and population section has been updated. |
| | Association of British Neurologists | Yes | Comment noted. |
| | The British Association for the Study of Headache | Yes | Comment noted. |

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| | The Migraine Trust | Yes | Comment noted. |
| Population | Association of British Neurologists | The population only mentions adults with chronic or episodic migraine. For such a new technology, episodic migraine should be considered in terms of high frequency (≥10 days/month) and low frequency (≤9 days/month) migraine.<br>However these cut-offs are somewhat arbitrary and we propose that future treatments should be assessed in terms of the whole migraine frequency spectrum e.g.<br>• 4-9 headache days/ month<br>• 10-15 headache days/ month<br>• 15-20 headache days/ month<br>• 20 plus headache days/ month<br>providing this does not reduce the power of statistical data and compromise comparison with comparator data which is fixed in the older parameters<br>The population should consider patients who have failed 3 or more prophylactic treatments in line with NICE TA 260 | Comments noted. Subgroups according to frequency of episodic migraine and number of previous prophylactic treatments are included in the 'other considerations section of the scope. No action required. |
| | The British Association for the Study of Headache | Migraine is a diverse illness ranging from infrequent and/or mild attacks to occurrence on a daily basis. The disease burden and cost to healthcare and economy in general varies, therefore, the migraine population should be divided into:<br>Chronic Migraine<br>Episodic Migraine – High frequency (9-14 days per month) – Low frequency (4-8 days per month) and infrequent ( < 4 days per month) | Comments noted. Subgroups according to frequency of episodic migraine and number of previous prophylactic treatments are included in the 'other considerations section of the scope. No action required. |

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| | The Migraine Trust | Yes | Comment noted. |
| Comparators | Eli Lilly | As Fremanezumab appraisal is ongoing we recommend inclusion as a comparator.<br>Fremanezumab (subject to ongoing NICE appraisal) | Comment noted. The comparator section of the scope has been revised. |
| | Novartis Pharmaceuticals UK Ltd | Fremanezumab (ID1368) (subject to ongoing NICE appraisal) should be added as a comparator. | Comment noted. The comparator section of the scope has been revised. |
| | Teva UK Limited | Teva requests that fremanezumab is included alongside erenumab as a comparator for this appraisal (including a similar disclaimer to erenumab that this subject to ongoing NICE appraisal) | Comment noted. The comparator section of the scope has been revised. |
| | Association of British Neurologists | Botulinum toxin A is licenced only for chronic migraine not episodic migraine.<br>A number of other standard prophylactic treatments are not described in the existing NICE guidance CG150 e.g. candesartan.<br>There is currently no head-to-head comparison between these options for care to describe which is 'best': overall benefit is based on both efficacy and lack of adverse effects.<br>We also recommend that this scope compares adherence and persistence to galcanezumab treatment with comparator preventative treatments: the real-life data on compliance with current first line comparators in the treatment of migraine has a major bearing on clinical effectiveness and may not have been adequately considered in previous appraisals of the use of CGRP | Comment noted. Candesartan is covered in the scope under "oral preventative treatments".<br>Details of available evidence to enable a direct and indirect comparison of galcanezumab and comparators will be covered in the company's evidence |

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| | | monoclonal antibody treatments for migraine (ref Hepp *et al* Cephalalgia 2017:37; 470–485) | submission. No action required. |
| | The British Association for the Study of Headache | The comparators for episodic migraine should also include candesartan widely used by the headache specialists and recommended in SIGN guidelines.<br>Botulinum toxin A is only a comparator in chronic migraine.<br>Acupuncture is recommended by NICE CG150 and could be a comparator for both episodic and chronic migraine.<br>If NICE is considering this appraisal post Erenumab and Fremanezumab decision, than these may be more reasonable comparators.<br>We suggest that any comparison must take into account the side effects, tolerability and adherence to any particular treatment.<br>The choice of prophylaxis is currently based on individual needs and co-morbidity as there are no head to head comparison between current prophylactic agents. | Comment noted. It is noted that best supportive care could cover a range of treatments and care. It is anticipated that the best supportive care in clinical practice in England would be determined during the appraisal.<br>The comparator section of the scope has been revised to include Fremanezumab (subject to ongoing NICE appraisal) |
| | The Migraine Trust | Yes | Comment noted. |
| Outcomes | Novartis Pharmaceuticals UK Ltd | Yes. These outcomes will capture the most important health related benefits and harms of the technology. | Comment noted. |
| | Association of British Neurologists | The subgroup with high frequency episodic migraine and chronic migraine have historically greater health-related quality of life (QoL) impairment and may see more clinically effective and cost effective outcomes compared with low frequency episodic migraine. | Comments noted. If the evidence allows, subgroups defined by type of migraine and |

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| | | It is important that a QoL measure looking at function, e.g. absenteeism from work, is also considered | frequency of episodic migraine will be considered. These subgroups are included in the 'other considerations' section of the scope. |
| | The British Association for the Study of Headache | The outcomes are different for chronic and high frequency episodic migraine compared to low frequency and infrequent episodic migraines.<br>Number of visits to the general practitioner or acute assessment units in the hospital including A & E are important in evaluating cost-effectiveness.<br>Health related quality of life measures including HIT-6, MIDAS, MSQ and EQ5-D can be used to evaluate change in disease burden following a treatment. | Comments noted. The list of outcomes is not exhaustive, more specific outcomes can be considered under the broad scope outcomes, as part of the full appraisal. All relevant resources should be included in the economic evaluation and this will be determined during the appraisal. |
| | The Migraine Trust | Yes | Comment noted. |
| Economic analysis | Eli Lilly | An economic analysis that addresses the requirements of NICE methods will be submitted. | Comment noted. |
| | Teva UK Limited | Teva requests that the following sentence is added to the scope to provide consistency with the scope for the ongoing appraisal of fremanezumab:<br>"The availability of any commercial arrangements for the intervention, | Comment noted. The Economic analysis |

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| | | comparator and subsequent treatment technologies will be taken into account." | section has been revised. |
| | Association of British Neurologists | The time horizon for episodic migraine is likely to be different from that for chronic migraine. For episodic migraine the time horizon may be at least 1-2 years, in contrast to chronic migraine where the it should be at least 3-5 years | Comment noted. Details of the time horizon will be included in the evidence submission and considered as part of the full appraisal. |
| | The British Association for the Study of Headache | There is very little published data on long term outcome for any treatment including the widely used oral prophylaxis. Unless real life data is available, it is reasonable to assume that treatment for episodic migraine is likely to be needed for 18-24 months before withdrawing treatment and longer for chronic migraine (3-5 years is the best estimate).<br>Economic analysis should also take into account access to service following recommendation as currently headache services are not equally available in different locations.<br>Economic analysis should also take into account the position of current recommendations i.e. after failure of one, two, three or more treatments. | Comment noted.<br>The reference case defined in the NICE guide to the methods of technology appraisal 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.<br>Subgroups defined by the number of previous preventive treatments will be considered if the evidence allows. |

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| | The Migraine Trust | Yes | Comment noted. |
| Equality and Diversity | Association of British Neurologists | No issues | Comment noted. |
| | The British Association for the Study of Headache | Women (22%) are affected three times more than men (8%), therefore any recommendation has more impact on the female gender.<br>Migraine is more common in the working age group and any decision on treatment is likely to impact more on the working population. | Comment noted. Only direct costs should be included, as specified in the reference case defined in the NICE guide to the methods of technology appraisal. The prevalence of this condition across genders is not expected to be an equality issue that can be addressed in a technology appraisal. |
| | The Migraine Trust | Migraine can be classed as a disability under the Equality Act 2010<br>Women are three times more likely to be affected by migraine and most common in people of working age. Therefore women who already face inequality in the work place are further disadvantaged by migraine.<br>The 2014 Headache Services report by the APPG on Primary Headache Disorders found that patients in England have non-equivocal access to specialist headache clinics and face barriers accessing appropriate and recommended treatments. | Comment noted. Migraines as a disability can be considered by the committee, if appropriate, at the time of the appraisal. The prevalence of this condition across genders is not expected to be an equality issue |

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| | | If Galcanezumab becomes available via a NICE recommendation, it should be more equitable in availability and access. | that can be addressed in a technology appraisal. |
| Other considerations | Association of British Neurologists | The efficacy in medication overuse headache should be considered | Comments noted. If evidence allows, other subgroups not listed in the scope should be presented in the evidence submissions for the committee to consider. |
| | The British Association for the Study of Headache | The appraisal should be based on current treatment practice in England & Wales.<br>Medication overuse is a common problem in patients with chronic and high frequency episodic migraines. | Comments noted. If evidence allows, other subgroups not listed in the scope should be presented in the evidence submissions for the committee to consider. |
| Innovation | Eli Lilly | There are currently no preventative drug treatment options which are specifically designed to reduce the frequency and severity of migraine attacks available on the NHS. Additionally a proportion of patients do not respond to or cannot take current oral preventatives due to safety/tolerability issues. Therefore, galcanezumab offers a step-change in the management of migraine for these patients. | Comments noted. Innovation will be considered in more detail as part of the full appraisal. |
| | Association of British Neurologists | Yes - this could be step change in the management of the condition for the following reasons: | Comments noted. Innovation will be considered in more |

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| | | 1. Better tolerated treatment compared with currently prescribed oral agents for migraine<br>2. Attractive adherence potential and rapid onset of action compared with historical preventative treatments.<br>The QALY calculation may not reflect a possible sub-group of 'super-responders' who have excellent results e.g. 75-100% headache response | detail as part of the full appraisal. |
| | The British Association for the Study of Headache | The CGRP MAB is a paradigm shift in managing migraine. These drugs are first ever migraine specific preventive treatments that has a potential of home care self-administered injections with side effect profile comparable to placebo and a very high tolerability and compliance. | Comments noted. Innovation will be considered in more detail as part of the full appraisal. |
| | The Migraine Trust | This technology is innovative in its potential to make a significant and substantial impact on health-related benefits and the way that current need is met. | Comments noted. Innovation will be considered in more detail as part of the full appraisal. |
| Questions for consultation | Eli Lilly | **How is galcanezumab expected to be used in clinical practice?**<br>• **Would it be used upfront as an alternative to oral preventive treatments or when there is an inadequate response to oral preventive treatments?**<br>We anticipate galcanezumab will be used in patients with an inadequate response to oral preventative treatments or in patients who have safety or tolerability concerns with oral preventative treatments.<br>**Have all relevant comparators for galcanezumab been included in the scope?** | Comment noted. The place in therapy will be considered in more detail as part of the full appraisal. |

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| | | • **Which treatments are considered to be established clinical practice in the NHS for preventing migraine?**<br><br>See comments in comparators box.<br><br>**Are the outcomes listed appropriate?**<br>We consider the outcomes listed appropriate.<br><br>**Are the subgroups suggested in 'other considerations' appropriate? Are there any other subgroups of people in whom galcanezumab is expected to be more clinically effective and cost effective or other groups that should be examined separately?**<br>We consider the subgroups suggested are appropriate and comprehensive.<br><br>**Where do you consider galcanezumab will fit into the existing NICE pathway, Headaches?**<br>We anticipate galcanezumab will be used in patients with an inadequate response to oral preventative treatments or in patients who have safety or tolerability concerns with oral preventative treatments.<br><br>**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:**<br>• **could exclude from full consideration any people protected by the equality legislation who fall within the patient population for which galcanezumab will be licensed;**<br><br>• **could lead to recommendations that have a different impact on people protected by the equality legislation than on the wider** | Comment noted.<br><br>Comment noted.<br><br>Comment noted.<br><br>Comment noted. The place in therapy will be considered in more detail as part of the full appraisal. |

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| | | **population, e.g. by making it more difficult in practice for a specific group to access the technology;**<br><br>• **could have any adverse impact on people with a particular disability or disabilities.**<br><br>**Please tell us what evidence should be obtained to enable the Committee to identify and consider such impacts.**<br>We have not identified any issues that would lead to inequality.<br><br>**Do you consider galcanezumab 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)?**<br><br>There are currently no preventative drug treatment options which are specifically designed to reduce the frequency and severity of migraine attacks available on the NHS. Additionally a proportion of patients do not respond or cannot take current oral preventatives due to safety/tolerability issues. Therefore, galcanezumab offers a step-change in management of migraine for these patients<br><br>**Do you consider that the use of galcanezumab can result in any potential significant and substantial health-related benefits that are unlikely to be included in the QALY calculation?**<br><br>**Please identify the nature of the data which you understand to be available to enable the Appraisal Committee to take account of these benefits.**<br><br>Migraine is associated with substantial lost productive time due to absenteeism and presenteeism. The galcanezumab clinical trial programme | Comment noted.<br><br>Comment noted. Innovation will be considered in more detail as part of the full appraisal. |

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| | | captures the impact of treatment on work productivity and activity via the Work Productivity and Activity Impairment (WPAI) and Migraine Disability Assessment (MIDAS)<br>Questionnaires. This is a key patient benefit that is unlikely to be fully captured in the QALY calculation.<br><br>**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.**<br><br>We do not anticipate any barriers to the adoption of galcanezumab into practice.<br><br>**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).**<br>We consider the STA process appropriate for galcanezumab. We also consider the FTA process may be appropriate (please see comments on cost comparison below).<br><br>**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.** | Comment noted. All aspects of health-related quality of life should be included in the evidence submissions for the committee to consider. |

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| | | • **Would it be appropriate to use the cost comparison methodology for this topic?**<br>It would be appropriate to use the cost-comparison methodology for this topic if comparators with similar health benefits are recommended in NICE technology appraisal guidance for the same indication at the time of submission.<br><br>• **Is the new technology likely to be similar in its clinical efficacy and resource use to any of the comparators?**<br>We anticipate galcanezumab will be similar in clinical efficacy and resource use to erenumab and fremanezumab.<br><br>• **Is the primary outcome that was measured in the trial or used to drive the model for the comparator(s) still clinically relevant?**<br>Yes<br><br>• **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?**<br><br>As stated above there is an ongoing trial (CONQUER; ClinicalTrials.gov Identifier: NCT03559257) assessing galcanezumab in adults with treatment-resistant migraine. We anticipate data from this trial will be available in [redacted]<br><br>Fremanezumab's FOCUS trial in patients with inadequate response to prior preventative treatments (ClinicalTrials.gov Identifier: NCT03308968) is estimated for completion in June 2019. | |
| | Novartis | *How is galcanezumab expected to be used in clinical practice?*<br>No comments | Comments noted. |

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| | | *Would it be used upfront as an alternative to oral preventive treatments or when there is an inadequate response to oral preventive treatments?*<br>No comments<br><br>*Have all relevant comparators for galcanezumab been included in the scope?*<br>Please see the comment above in the 'Comparators' section regarding the potential for addition of fremanezumab as an appropriate comparator.<br><br>*Which treatments are considered to be established clinical practice in the NHS for preventing migraine?*<br><br>NICE Headache Guidelines (CG150, 2015) recommend offering topiramate or propranolol for the prophylactic treatment of migraine according to the person's preference, comorbidities and risk of adverse events[1]. The 'Management of Migraine (with or without aura)' section of the NICE Headache Pathway also states to consider amitriptyline[2] for the prophylactic treatment of migraine according to the person's preference, comorbidities and risk of adverse events. Botulinum toxin type A is also recommended as an option for the prophylaxis of headaches in adults with chronic migraine that has not responded to at least three prior pharmacological prophylaxis therapies and whose condition is appropriately managed for medication overuse[3]. British Association for the Study of Headache (BASH) Guideline recommends various prophylactic treatment options[4].<br>1. NICE Clinical Guideline. Headaches in over 12s: diagnosis and Management (CG150), September 2012 https://www.nice.org.uk/guidance/cg150<br>2. NICE Pathway, 'Management of Migraine (with or without aura)' https://pathways.nice.org.uk/pathways/headaches/management-of-migraine-with-or-without-aura<br>3. NICE TA 260 https://www.nice.org.uk/guidance/ta260<br>4. BASH - Guidelines for All Healthcare Professionals in the Diagnosis and Management of Migraine<br>Tension-Type Headache Cluster Headache | Galcanezumab will be assessed in comparison with what is being used in clinical practice at the time of the appraisal. |

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| | | Medication-Overuse Headache. 3rd edition (1st revision) 2010 http://www.bash.org.uk/wp-content/uploads/2012/07/10102-BASH-Guidelines-update-2_v5-1-indd.pdf<br><br>*Are the outcomes listed appropriate?*<br>No comments.<br><br>*Are the subgroups suggested in 'other considerations' appropriate? Are there any other subgroups of people in whom galcanezumab is expected to be more clinically effective and cost effective or other groups that should be examined separately*?<br>No comments.<br><br>*Where do you consider galcanezumab will fit into the existing NICE pathway, Headaches?*<br>Pending the outcome of this appraisal we would envisage that galcanezumab will fit within the 'migraine prophylaxis' section of the 'Headache' pathway.<br><br>*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.*<br>No comments.<br><br>*Do you consider galcanezumab 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)?*<br>No comments. | |

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| | | *Do you consider that the use of galcanezumab can result in any potential significant and substantial health-related benefits that are unlikely to be included in the QALY calculation?*<br>No comments.<br><br>*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.*<br>No comments.<br><br>*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).*<br><br>We consider an STA to be the appropriate NICE assessment route.<br><br>*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.*<br>*Would it be appropriate to use the cost comparison methodology for this topic?*<br><br>A cost comparison methodology would only be appropriate if galcanezumab has similar health effects and similar costs to a NICE approved comparator, and could therefore be recommended for use in the same patient population as that comparator. As we are not the manufacturer of this technology, we cannot comment on whether this is expected to be the case. | |

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| | | *Is the new technology likely to be similar in its clinical efficacy and resource use to any of the comparators?*<br>As we are not the manufacturer of this technology, we cannot comment on whether this is expected to be the case.<br><br>*Is the primary outcome that was measured in the trial or used to drive the model for the comparator(s) still clinically relevant?*<br>No comment.<br><br>*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?*<br>No comment. | This will be assessed in detail as part of the full appraisal. |
| | Association of British Neurologists | It is anticipated that such a new technology will be used in secondary care for patients with disabling chronic migraine who have tried at least 3 standard preventative medications. It may be used as an alternative to botulinum toxin treatment, although the anticipated higher cost of galcanezumab may place it to be used after a trial of botulinum toxin.<br><br>It is not yet known whether galcanezumab will be effective in patients with medication overuse headache but standard practice and other NICE guidelines e.g. CG150 recommends that patients are appropriately managed | Comment noted. The place in therapy will be considered in more detail as part of the full appraisal. |

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| | | for mediation overuse headache before escalating prophylactic treatment options.<br><br>The outcomes listed are appropriate but 'health-related QoL' should include reference to the functional impact and the huge economic burden from migraine to the UK economy in terms of absenteeism and reduced productivity at work. Migraine specific questionnaires such as MIDAS reflect these issues to an extent. | The NICE reference case stipulates that the perspective on costs should be that of the NHS and Personal Social Services. Please see NICE guide to the methods of technology appraisal for more information. |
| | The British Association for the Study of Headache | Considering Galcanezumab (like other CGRP MAB) will be a high cost drug, it is likely to be used in secondary care following failure of first line treatments. However, in patients with chronic migraine its place before or after Botulinum Toxin requires careful health economic evaluation.<br>The place for Galcanezumab in the NICE pathway depends on the outcome of other CGRP MAB TAG. | Comment noted. The place in therapy will be considered in more detail as part of the full appraisal. |
| | The Migraine Trust | The Questions are appropriate. | Comment noted. |

**The following consultees/commentators indicated that they had no comments on the draft remit and/or the draft scope**

Department of Health and Social Care

*Association of British Neurologists response endorsed by Royal College of Physicians