

3-year scoping report

Topic: Pharmacological management of migraine: literature published since date of SIGN 155 guideline search in 2016

Date of search: 4 to 6 October

Searched by: Iain Colthart

Key concepts: Migraine disorders, migrain\$, medication-overuse headache

Summary of findings

The purpose of this 3-year scoping is to identify significant new evidence relating to SIGN 155, and whether any sections of the guideline require updating. A rapid search of the literature was conducted; sources and references are detailed in the box below.

Chair's comments

Comment
<p>The Chair submitted an evidence support request indicating areas in the guidance that required review and updating. Specifically trials have now been completed on a new therapy, Calcitonin gene related peptide (CGRP) monoclonal antibodies for the treatment of patients with migraine. The trials were ongoing when the guideline was under development and it was agreed that these would be addressed in an update once the trials and SMC advice had been published.</p> <p>In relation to this, SMC has published advice on erenumab (March 2019), fremanezumab (January 2020), galcanezumab (April 2021). This has been strengthened by the publication of NICE guidance on these respective CGRPs. This advice could be considered for incorporation in to an updated guideline.</p>

Relevant evidence and implications for SIGN recommendations

SIGN section 4.15 Calcitonin gene-related peptide

Reference	Details	How does this potentially change current recommendations?
<p>Sacco, S., et al. (2019). "European headache federation guideline on the use of monoclonal antibodies acting on the calcitonin gene related peptide or its receptor for migraine prevention." The Journal of Headache and Pain 20(1): 6. DOI: https://dx.doi.org/10.1186/s10194-018-0955-y</p>	<p>Advice and guidance on erenumab, fremanezumab and galcanezumab.</p> <p>The literature review within the guideline found low to high quality of evidence to recommend eptinezumab, erenumab, fremanezumab, and galcanezumab in patients with episodic migraine and medium to high quality of evidence to recommend erenumab, fremanezumab, and galcanezumab in patients with chronic migraine.</p>	<p>Relevant to section 4.15 - Calcitonin gene-related peptide.</p> <p>The SIGN guideline identified four phase 2 RCTs and 2 phase 3 RCTs demonstrating that CGRP monoclonal antibodies were more effective than placebo and safe. At the point the guideline was being published assessment by regulatory bodies and the results of further phase 3 trials were awaited.</p> <p>Sacco et al. update the evidence which was known at the time of the SIGN guideline's publication. On the basis of this evidence the guideline could be updated to incorporate the inclusion of erenumab, fremanezumab, and galcanezumab</p>

SIGN section 4.15 Calcitonin gene-related peptide - erenumab

Reference	Details	How does this potentially change current recommendations?
<p>SMC 2134</p> <p>erenumab 70mg solution for injection in pre-filled pen (Aimovig®)</p>	<p>In four studies in patients with episodic and chronic migraine, erenumab significantly reduced the number of migraine days per month compared with placebo.</p>	<p>Provides new evidence for section 4.15 from the results of clinical trials which were awaited at the time of the guideline's</p>

<p>Published 8/4/19</p> <p>https://www.scottishmedicines.org.uk/medicines-advice/erenumab-aimovig-full-submission-smc2134/</p>	<p>ARISE study for episodic migraine: Patients receiving 70mg erenumab experienced -2.9 days change in monthly migraine days (MMD), compared with -1.8 days for placebo, least-squares mean (95% CI) treatment difference of -1.0 (-1.6, -0.5) ($p < 0.001$).</p> <p>STRIVE study (in Episodic Migraine): Patients receiving 70mg erenumab experienced -3.2 days change in MMD, compared with -1.8 days for placebo, least-squares mean (95% CI) treatment difference of -1.4 (-1.9, -0.9) ($p < 0.001$).</p> <p>Patients receiving 140mg erenumab experienced -3.7 days change in MMD, compared with -1.8 days for placebo, least-squares mean (95% CI) treatment difference of -1.9 (-2.3, -1.4) ($p < 0.001$).</p> <p>LIBERTY study (in Episodic Migraine): Patients receiving 140mg erenumab experienced -1.8 days change in MMD, compared with -0.2 days for placebo, least-squares mean (95% CI) treatment difference of -1.6 (-2.7, -0.5) ($p = 0.004$).</p> <p>Study 295 study (in Chronic Migraine): Patients receiving 70mg erenumab experienced -6.6 days change in MMD, compared with -4.2 days for placebo, least-squares mean (95% CI) treatment difference of -2.5 (-3.5, -1.4) ($p < 0.0001$).</p> <p>Patients receiving 140mg erenumab experienced -6.6 days change in MMD, compared with -4.2 days for placebo, least-squares mean (95% CI)</p>	<p>publication and advice on the use of erenumab.</p> <p>SMC guidance: Erenumab is accepted for restricted use within NHSScotland for prophylaxis of migraine in adults who have at least 4 migraine days per month. SMC restriction: for patients with chronic migraine and in whom at least three prior prophylactic treatments have failed.</p> <p>Erenumab could be considered for inclusion in SIGN 155.</p>
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	treatment difference of -2.5 (-3.5, -1.4) (p<0.0001).	
<p>NICE Technology appraisal guidance</p> <p>Erenumab for preventing migraine (TA682)</p> <p>Published 10/3/21</p> <p>www.nice.org.uk/guidance/ta682</p>	<p>Draws on evidence from the ARISE, STRIVE, LIBERTY and Study 295 trials detailed above in SMC evidence.</p> <p>For people whose migraine has not responded to at least 3 preventive treatments, the clinical trial evidence shows that erenumab 140 mg works better than best supportive care for preventing chronic or episodic migraine.</p> <p>Erenumab 140 mg is clinically effective for chronic migraine compared with best supportive care but less so at 70 mg.</p> <p>Study 295 trial results showed that erenumab 140 mg reduced the number of monthly migraine days from baseline to week 12 by 4.1 days more on average than placebo (95% confidence interval [CI] -5.8 to -2.3). The 70 mg dosage reduced monthly migraine days by 2.5 days more on average than placebo (95% CI -4.3 to -0.8). The proportion of people with at least a 50% reduction in monthly migraine days was 38.5% for the 140 mg dosage, 34.8% for the 70 mg dosage, and 15.3% for placebo. The results were statistically significant. The committee recognised that erenumab 140 mg also improved other outcomes compared with placebo, including the severity of migraine pain and the number of headache days each month. It noted that erenumab 140 mg reduced monthly migraine days compared with</p>	<p>Provides new evidence for section 4.15 from the results of clinical trials which were awaited at the time of the guideline's publication and advice on the use of erenumab.</p> <p>Erenumab 140 mg is clinically effective for chronic migraine compared with best supportive care but less so at 70 mg.</p> <p>Erenumab 140 mg may be clinically effective for episodic migraine compared with best supportive care but erenumab 70 mg is not.</p> <p>NICE recommendation is that erenumab is indicated for prophylaxis of migraine in adults who have at least 4 migraine days per month</p> <p>Erenumab could be considered for inclusion in SIGN 155.</p>

	<p>placebo more than the 70 mg dosage compared with placebo.</p> <p>Erenumab 140 mg may be clinically effective for episodic migraine compared with best supportive care but erenumab 70 mg is not.</p> <p>The STRIVE, ARISE and LIBERTY trials compared erenumab with placebo in 1,778 people with episodic migraine. A post-hoc subgroup analysis was done to show erenumab's effectiveness in people for whom at least 3 previous treatments had failed. Erenumab was also more effective than placebo in reducing the number of monthly migraine days from baseline to week 12. The results were statistically significant for the 140 mg dose in STRIVE but not in LIBERTY (ARISE only studied the 70 mg dose).</p> <p>The committee also noted that none of the results for the 70 mg dosage were statistically significant. The committee concluded that erenumab 140 mg may be clinically effective for episodic migraine when compared with best supportive care but there was no evidence that the 70 mg dosage was clinically effective.</p>	
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SIGN section 4.15 Calcitonin gene-related peptide - fremanezumab

Reference	Details	How does this potentially change current recommendations?
<p>SMC2226</p> <p>Fremanezumab 225mg solution for injection in pre-filled syringe</p> <p>Published 13/1/20</p> <p>https://www.scottishmedicines.org.uk/medicines-advice/fremanezumab-ajovy-full-smc2226/</p>	<p>Three phase III studies demonstrated superiority of fremanezumab over placebo in reducing the number of monthly migraine days in patients with chronic and episodic migraine.</p> <p>The key evidence to support the efficacy and safety of fremanezumab came from a randomised, double-blind, placebo-controlled, phase IIIb study (FOCUS) in patients with episodic and chronic migraine who had an inadequate response to two to four previous classes of preventive therapy.</p> <p>Patients were randomised equally to fremanezumab 675mg subcutaneously administered once every three months (n=276), fremanezumab 225mg subcutaneously monthly (except patients with chronic migraine who received 675mg in month 1 only, n=283), or placebo (n=279) for 12 weeks. Patients in all treatment groups received matching placebo injections to maintain blinding.</p> <p>The primary outcome was mean change from baseline in the monthly average number of migraine days during the 12-week treatment period.</p>	<p>Provides new evidence for section 4.15 from the results of clinical trials which were awaited at the time of the guideline’s publication and guidance on the use of fremanezumab.</p> <p>SMC guidance: fremanezumab is accepted for restricted use within NHSScotland for prophylaxis of migraine in adults who have at least 4 migraine days per month.</p> <p>SMC restriction: for the treatment of patients with chronic and episodic migraine who have had prior failure on three or more migraine preventive treatments.</p> <p>Fremanezumab could be considered for inclusion in SIGN 155.</p>

	<p>Patients receiving 225mg fremanezumab monthly experienced -4.1 days change in monthly migraine days over 12 weeks, compared with -0.6 days for placebo, least-squares mean (95% CI) treatment difference of -3.5 (-4.2, -2.8) ($p < 0.001$).</p> <p>Patients receiving 675mg fremanezumab quarterly experienced -3.7 days change in monthly migraine days over 12 weeks, compared with -0.6 days for placebo, least-squares mean (95% CI) treatment difference of -3.1 (-3.8, -2.4) ($p < 0.001$).</p> <p>Two other randomised, double-blind, phase III studies demonstrated the superiority of both fremanezumab regimens over placebo in patients with episodic migraine (HALO EM) and patients with chronic migraine (HALO CM). The primary outcome of HALO-CM and HALO-EM were monthly average number of headache days of at least moderate severity, and monthly average number of migraine days, respectively.</p>	
<p>NICE Technology appraisal guidance</p> <p>Fremanezumab for preventing migraine (TA631)</p> <p>Published 3/6/20</p> <p>https://www.nice.org.uk/guidance/ta631</p>	<p>Draws on evidence from the FOCUS, HALO CM and HALO EM trials detailed above in SMC evidence.</p> <p>For people whose migraine has not responded to at least 3 oral preventive treatments, clinical trial evidence shows that fremanezumab works better than best supportive care in both episodic and chronic migraine.</p> <p>For chronic migraine, assuming fremanezumab works better than botulinum toxin type A, the</p>	<p>Provides new evidence for section 4.15 from the results of clinical trials which were awaited at the time of the guideline's publication and guidance on the use of fremanezumab.</p> <p>Fremanezumab for chronic migraine is recommended for use in the NHS</p> <p>Fremanezumab for episodic migraine is not recommended for use in the NHS</p>

	<p>most likely cost-effectiveness estimates are within the range NICE normally considers an acceptable use of NHS resources. So it is recommended for chronic migraine. In line with clinical practice, fremanezumab treatment should stop if it is not working well enough after 12 weeks.</p> <p>For episodic migraine, uncertainty in the economic modelling about stopping treatment and quality of life affects the cost-effectiveness estimates. The most likely estimates for fremanezumab are higher than what NICE normally considers an acceptable use of NHS resources. So it is not recommended for episodic migraine.</p>	<p>Differs from SMC advice which recommends the use of fremanezumab for both episodic and chronic migraine. NICE do not recommend use for the treatment of episodic migraine due to uncertainty over economic modelling of cost-effectiveness estimates.</p> <p>Fremanezumab could be considered for inclusion in SIGN 155.</p>
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SIGN section 4.15 Calcitonin gene-related peptide – Galcanezumab

Reference	Details	How does this potentially change current recommendations?
<p>SMC2313</p> <p>Galcanezumab (Emgality)</p> <p>Published 12/4/21</p> <p>https://www.scottishmedicines.org.uk/medicines-advice/galcanezumab-emgality-full-smc2313/</p>	<p>In studies in patients with episodic and chronic migraine, galcanezumab significantly reduced the number of migraine days per month compared with placebo.</p> <p>Reports evidence from 3 double-blind phase III studies which recruited adults with chronic migraine (REGAIN), episodic migraine (EVOLVE-1 and -2) and both chronic and episodic migraine (CONQUER), with the latter study only</p>	<p>Provides new evidence for section 4.15 and guidance on the use of galcanezumab.</p> <p>SMC guidance: galcanezumab is accepted for restricted use within NHSScotland for prophylaxis of migraine in adults who have at least 4 migraine days per month.</p>

	<p>recruiting those who had failed 2 to 4 migraine prevention therapies.</p> <p>Results for the licensed dose (galcanezumab 120mg) only are presented. In all studies the primary outcome, overall mean change from baseline in monthly migraine headache days (MHD) during the treatment period was significantly improved versus placebo with galcanezumab 120mg in the ITT population</p> <p>CONQUER: Chronic and episodic migraine Patients receiving galcanezumab experienced -4.1 days change in MHD compared with -1.0 days for placebo, least-squares mean (95% CI) treatment difference of -3.1 (-3.9 to -2.3)</p> <p>CONQUER: Episodic migraine subgroup Patients receiving galcanezumab experienced -2.9 days change in MHD compared with -0.3 days for placebo, least-squares mean (95% CI) treatment difference of -2.6 (-3.4 to -1.7)</p> <p>CONQUER: Chronic migraine subgroup Patients receiving galcanezumab experienced -6.0 days change in MHD compared with -2.2 days for placebo, least-squares mean (95% CI) treatment difference of -3.7 (-5.2 to -2.2)</p> <p>REGAIN: Chronic migraine Patients receiving galcanezumab experienced -4.8 days change in MHD compared with -2.7 days for placebo, least-squares mean (95% CI) treatment difference of -2.1 (-2.9 to -1.3)</p>	<p>SMC restriction: for the treatment of patients with chronic and episodic migraine who have had prior failure on three or more migraine preventive treatments.</p> <p>Galcanezumab should be considered for inclusion in SIGN 155.</p>
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	<p>EVOLVE-1: Episodic migraine Patients receiving galcanezumab experienced -4.7 days change in MHD compared with -2.8 days for placebo, least-squares mean (95% CI) treatment difference of -1.9 (-2.5 to -1.4)</p> <p>EVOLVE-2: Episodic migraine Patients receiving galcanezumab experienced -4.3 days change in MHD compared with -2.3 days for placebo, least-squares mean (95% CI) treatment difference of -2.0 (-2.5 to -1.5)</p>	
<p>NICE Technology appraisal guidance</p> <p>Galcanezumab for preventing migraine (TA659)</p> <p>Published 18/11/20</p> <p>https://www.nice.org.uk/guidance/ta659</p>	<p>For migraine that has not responded to at least 3 preventive treatments, clinical trial evidence shows that galcanezumab works better than best supportive care in both episodic and chronic migraine</p> <p>Draws on evidence from the CONQUER, REGAIN, EVOLVE-1 and EVOLVE-2 trials detailed above in SMC evidence.</p> <p>The results showed:</p> <p>galcanezumab reduced the number of monthly migraine days more than placebo for episodic and chronic migraine</p> <p>galcanezumab reduced the number of monthly headache days more than placebo for episodic and chronic migraine</p> <p>more people having galcanezumab had a reduction of at least 50% in the average monthly number of migraine days compared with placebo for episodic migraine</p>	<p>Provides new evidence for section 4.15 and guidance on the use of galcanezumab.</p> <p>Galcanezumab is indicated for the prophylaxis of migraine in adults who have at least 4 migraine days per month.</p> <p>It is plausible that galcanezumab may work better than botulinum toxin type A.</p> <p>Galcanezumab should be considered for inclusion in SIGN 155.</p>

	<p>more people having galcanezumab had a reduction of at least 30% in the average monthly number of migraine days compared with placebo for chronic migraine.</p> <p>Evidence from the CONQUER trial suggests galcanezumab may be clinically effective for chronic migraine after failure of 3 preventive treatments and botulinum toxin type A. However there is uncertainty in the evidence.</p>	
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SIGN section 4.3 - Topiramate

Reference	Details	How does this potentially change current recommendations?
<p>NICE Clinical Guidance</p> <p>Headaches in over 12s: diagnosis and management (CG150) 2012 (updated 2021)</p> <p>https://www.nice.org.uk/guidance/cg150</p>	<p>The updated clinical guidance incorporates MHRA advice on antiepileptic drugs in pregnancy: In May 2021, recommendations on topiramate were updated for migraine prophylaxis to include discussion of the potential benefits and risks, and the importance of effective contraception for women and girls of childbearing potential when taking topiramate.</p>	<p>Strengthens the evidence in section 4.3 regarding the use of topiramate which states that: “Before commencing treatment women who may become pregnant should be advised of the associated risks of topiramate during pregnancy, the need to use effective contraception and the need to seek further advice on migraine prophylaxis if pregnant or planning a pregnancy”</p>

SIGN section 5 – Medication over-use headache

Reference	Details	How does this potentially change current recommendations?
<p>Diener, H. C., et al. (2020). "European Academy of Neurology guideline on the management of medication-overuse headache." <i>European Journal of Neurology</i> 27(7): 1102-1116.</p> <p>https://doi.org/10.1111/ene.14268</p>	<p>Reviews the evidence in relation to the following questions on MoH:</p> <ol style="list-style-type: none"> 1. Are information and education effective for the prevention of MOH in patients at risk? 2. Is pharmacological preventive therapy effective in the prevention of MOH in patients at risk? 3. Are education and counselling effective in the treatment of MOH? 4. Is preventive medical and non-medical treatment effective in MOH? 5. Is withdrawal from overused medication(s) effective in MOH? 6. Can the symptoms that subjects with MOH develop during medication withdrawal be treated? 7. Can relapse after successful treatment of MOH be prevented? 	<p>How does this potentially change current recommendations?</p> <p>May provide evidence to supplement section 5.</p> <p>For example: The author’s recommendation (albeit based on their own experience rather than cited evidence) of the benefit of providing an information brochure and education about the potential relationship between frequent use of pain medications and the transition from episodic to chronic headache may be effective in preventing MOH in at-risk patients with migraine.</p> <p>Notes the moderate evidence supporting the use of erenumab in treating MOH</p> <p>In relation to the question in SIGN 155 about where detoxication is best achieved in primary care, specialised (neurology) outpatient care or in-hospital care the authors state that “Withdrawal can be performed on an outpatient basis, in a daycare setting or an inpatient setting. All settings have a similar success rate because of the different complexities suited for each setting. Headache history may help to assign patients to a particular setting.” However it is not clear what specific evidence this is based on.</p>

Recommendations for research

Reference	Details	What area for further research does this address?
None identified		

Potentially important new evidence

Reference	Details	Why might this be important to include in the guideline?
<p>Goadsby PJ, Wietecha LA, Dennehy EB, Kuca B, Case MG, Aurora SK, Gaul C. Phase 3 randomized, placebo-controlled, double-blind study of lasmiditan for acute treatment of migraine. <i>Brain</i>. 2019 Jul 1;142(7):1894-1904. https://pubmed.ncbi.nlm.nih.gov/31132795/</p>	<p>Lasmiditan</p> <p>This prospective, double-blind, phase 3 multicentre study randomly assigned patients with migraine with and without aura (1:1:1:1 ratio) to oral lasmiditan 200 mg, 100 mg, 50 mg, or placebo. Patients were instructed to dose at home within 4 h of onset of migraine attack of at least moderate intensity and not improving. The primary objective was to assess the proportion of patients' headache pain-free and most bothersome symptom-free at 2 h post-dose for each dose of lasmiditan versus placebo (NCT02605174). Patients (n = 3005) were assigned and treated (n = 2583, safety population): 1938 lasmiditan (200 mg n = 528, 100 mg n = 532, and 50 mg n = 556 included in primary analysis) and 645 placebo (540 included in primary analysis). Most patients (79.2%) had ≥ 1</p>	<p>Lasmiditan is a high-affinity, highly selective 5-HT_{1F} receptor agonist that acts on the trigeminal system. Lasmiditan is approved by the FDA for the acute (active but short-term) treatment of migraine with or without aura. Two randomised, double-blind, placebo-controlled, phase 3 trials demonstrated that lasmiditan was effective (in terms of patients who were free of headache pain and free of their most bothersome symptom at 2 hours after dosing) and well tolerated for the treatment of acute migraine in patients with a high level of cardiovascular risk factors</p> <p>Cross reference with NICE Technology Appraisal Guidance for Lasmiditan for treating acute migraine Expected publication date: 29 March 2023.</p>

	<p>cardiovascular risk factor at baseline, in addition to migraine. Lasmiditan was associated with significantly more pain freedom at 2 h (lasmiditan 200 mg: 38.8%, odds ratio 2.3, 95% confidence interval 1.8–3.1, $P < 0.001$; 100 mg: 31.4%, odds ratio 1.7, 1.3–2.2, $P < 0.001$; 50 mg: 28.6%, odds ratio 1.5, 1.1–1.9, $P = 0.003$ versus placebo 21.3%) and freedom from most bothersome symptom at 2 h (lasmiditan 200 mg: 48.7%, odds ratio 1.9, 95% confidence interval 1.4–2.4, $P < 0.001$; 100 mg: 44.2%, odds ratio 1.6, 1.2–2.0, $P < 0.001$; 50 mg: 40.8%, odds ratio 1.4, 1.1–1.8, $P = 0.009$ versus placebo 33.5%). Treatment-emergent adverse events were reported in 253 of 649 (39.0%), 229 of 635 (36.1%), and 166 of 654 (25.4%) of patients on lasmiditan 200, 100, and 50 mg, respectively, versus 75 of 645 (11.6%) on placebo. Most adverse events were CNS-related and included dizziness, somnolence and paraesthesia. Lasmiditan was effective at 2 h post-dose for acute treatment of migraine at all oral doses tested. Efficacy and safety were consistent with the previous phase 3 study.</p>	
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Consultation feedback

Former members of the SIGN 155 guideline development group were invited to comment on the report and the proposed areas for update.

Reviewer	Comments
Dr Callum Duncan, Consultant Neurologist, Aberdeen Royal Infirmary, Chair, SIGN 155	<ol style="list-style-type: none">1. We should update SIGN 155 with the evidence presented for CGRP Monoclonal antibodies. These are an important new development and have gone through both the SMC and NICE process. This is the main reason for the update.2. While we are reviewing the CGRP monoclonals it would be worth reviewing the Topiramate and MOH paper to see whether we should add in more information.3. Lasmitidan and the gpants will come on the scene in the next few years but if the projected time scale for Lasmitidan for NICE is March 2023 and the SMC have not set a date then I do not think we should delay, but it is likely we will need another focused update in a subsequent 3 years.
Dr Javier Carod Artel, Consultant Neurologist, Raigmore Hospital, Inverness	I have read the report and in my view, I feel it is important to update the Migraine SIGN guideline with the clinical trials about the use of anti-CGRP therapies for the prevention of migraine. As this is a qualitative change in the management of migraine, I believe that the efficacy and safety aspects of these drugs (erenumab, fremanezumab and galcanezumab) should be updated and included in the revised guideline.
Dr David Watson, GP with Special Interest in Headache, Aberdeen	I agree that SIGN 155 needs updated to include the monoclonals with the evidence base that is attached and the recommendations as per SMC. We have been using them now over 18 months and I hope are on most NHS Boards' formularies . I think the contraceptive advice about topiramate is useful. Would be interesting to know if lasmiditan is being submitted to SMC.

Concluding remarks

When the guideline was developed there were trials underway for a new therapy, Calcitonin gene related peptide (CGRP) monoclonal antibodies. As the evidence and SMC advice on CGRP monoclonal antibodies is now published, this section of the guideline requires an update to ensure the guideline remains current.

The recommendation is:

In the light of the new evidence selected elements of the guideline should be reviewed.

Decision

The recommendation was ratified by SMT on 1 December 2021.

This guideline is in need of review and has been accepted onto the SIGN guideline programme.
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Annex 1

Evidence sources

Resource	Results
Dynamed	Diener, H.C., Antonaci, F., Braschinsky, M., Evers, S., Jensen, R., Lainez, M., Kristoffersen, E.S., Tassorelli, C., Ryliskiene, K., Petersen, J.A., 2020. European Academy of Neurology guideline on the management of medication-overuse headache. European Journal of Neurology 27, 1102–1116.. doi:10.1111/ene.14268
BMJ Best Practice	Goadsby PJ, Wietecha LA, Dennehy EB, Kuca B, Case MG, Aurora SK, Gaul C. Phase 3 randomized, placebo-controlled, double-blind study of lasmiditan for acute treatment of migraine. Brain. 2019 Jul 1;142(7):1894-1904. https://pubmed.ncbi.nlm.nih.gov/31132795/ Headache Classification Committee of the International Headache Society (IHS) 2018. The International Classification of Headache Disorders, 3rd edition. Cephalalgia 38, 1–211. doi:10.1177/0333102417738202 https://journals.sagepub.com/doi/full/10.1177/0333102417738202
Guidelines and guidance	
Previous HIS projects/advice/guidance relating to this topic	SMC2134 Erenumab (Aimovig) 08/04/2019 https://www.scottishmedicines.org.uk/medicines-advice/erenumab-aimovig-full-submission-smc2134/ SMC2226 Fremanezumab (Ajovy) 13/01/2020 https://www.scottishmedicines.org.uk/medicines-advice/fremanezumab-ajovy-full-smc2226/ SMC2313 Galcanezumab (Emgality) 12/04/2021 https://www.scottishmedicines.org.uk/medicines-advice/galcanezumab-emgality-full-smc2313/

[NICE](#)

Technology Appraisal Guidance

Published

Galcanezumab for preventing migraine (TA659) 2020
<https://www.nice.org.uk/guidance/ta659>

Fremanezumab for preventing migraine (TA631) 2020
<https://www.nice.org.uk/guidance/ta631>

Erenumab for preventing migraine (TA682) 2021
<https://www.nice.org.uk/guidance/ta682>

In development

Rimegepant for treating or preventing migraine (ID1539)
In development (GID-TA10839)
Expected publication date: 10 August 2022
<https://www.nice.org.uk/guidance/indevelopment/gid-ta10839>

Lasmiditan for treating acute migraine (ID3759)
In development (GID-TA10807)
Expected publication date: 29 March 2023
<https://www.nice.org.uk/guidance/indevelopment/gid-ta10807>

Proposed

Eptinezumab for preventing migraine (ID3803)
Proposed (GID-TA10677)
Expected publication date: TBC
<https://www.nice.org.uk/guidance/proposed/gid-ta10677>

Interventional Procedure Guidance

	<p>Under consultation Transcutaneous electrical stimulation of the supraorbital nerve for treating and preventing migraine - in development (GID-IPG10175) Consultation closed 18 October 2021, publication date tbc https://www.nice.org.uk/guidance/indevelopment/gid-ipg10175/consultation/html-content</p> <p>Clinical Guideline Headaches in over 12s: diagnosis and management (CG150) 2012 (updated 2021) https://www.nice.org.uk/guidance/cg150</p>
HTW	None identified
HTA database	None identified
Additional searching (if required)	
Cochrane library	<p>Herd CP, Tomlinson CL, Rick C, Scotton WJ, Edwards J, Ives N, Clarke CE, Sinclair A. Botulinum toxins for the prevention of migraine in adults. Cochrane Database of Systematic Reviews 2018, Issue 6. Art. No.: CD011616. https://www.cochranelibrary.com/cdsr/doi/10.1002/14651858.CD011616.pub2/full</p>
Medline	<p>Sacco, S., et al. (2019). "European headache federation guideline on the use of monoclonal antibodies acting on the calcitonin gene related peptide or its receptor for migraine prevention." The Journal of Headache and Pain 20(1): 6. DOI: https://dx.doi.org/10.1186/s10194-018-0955-y</p>