South East Regional Medicines Optimisation Group (SERMOG) policy recommendation

Title:	Anti-CGRP and botulinum toxin type A migraine prevention pathway
Number:	SERMOG-08
Category:	Treatment pathway
Date determined by SERMOG:	July 2025

Introduction

This pathway is a guideline for the use of anti-calcitonin gene related peptide (anti-CGRP) medicines and botulinum toxin type A for the prevention of migraines. The pathway follows NICE Technology Appraisal (TA) guidance and regional recommendations. All medications and dosing regimens detailed are licenced.

NICE Clinical Guideline on the diagnosis and management of headaches in over 12s (CG150) recommends considering the use of a headache diary (to aid in the diagnosis of migraine) by recording the frequency, duration and severity of headaches, to monitor the effectiveness of headache interventions and as a basis for discussion with the person about their headache disorder and its impact. Furthermore, the guidance states to be alert to the possibility of medication overuse headache in people whose headache developed or worsened while they were taking the following drugs for 3 months or more:

- Triptans, opioids, ergots or combination analgesic medications on 10 days per month or more OR
- Paracetamol, aspirin or an non-steroidal anti-inflammatory drugs (NSAID), either alone or in any combination, on 15 days per month or more.

The drugs listed in this pathway are not disease modifying; therefore, it could be useful to consider the impact of lifestyle factors such as sleep pattern, regular exercise, regular meals and good hydration, caffeine overuse, maintaining a headache diary, stress management, BMI optimisation and avoiding migraine triggers.

The use of anti-CGRP medicines and botulinum toxin type A for the prevention of migraines is only approved in line with this pathway and the dosing regimens outlined in Table 3. Any dose regimens outside of these recommendations are not routinely funded, as detailed in SERMOG-02 (Overarching policy on licensed doses or dosing schedules of high-cost drugs not considered in NICE TA guidance).

As detailed in Table 3, there are six anti-CGRP medicines, utilising two mechanisms of action and three different methods of administrations which have been recommended by NICE TAs for the prevention of migraine. Due to the absence of good quality clinical evidence of the efficacy of sequential use of these medicines the SERMOG recommend best practice guidance that if a patient fails to adequately respond to the first anti-CGRP treatment a second may be trialled. Beyond this, clinicians should be aware that there is an absence of good quality clinical evidence that further treatment trials of anti-CGRP treatments will result in a clinically meaningful response. If patients require a change of medication due to intolerance/ adverse events, this should not count towards the number of treatments trialled. This guidance does not apply for switching between anti-CGRP medications and botulinum toxin type A or vice-versa.

The most appropriate treatment should be chosen after discussing the advantages and disadvantages of the therapies available with the person having treatment. If patients and clinicians consider more than one treatment to be suitable, the least expensive treatment should be used (taking into account drug administration costs, dose needed and frequency, and product price per dose). The lowest cost treatments are highlighted in Table 2 and cost tiers are given in Table 3.

Where biosimilars become available, these should be used, as detailed in SERMOG-03 (Overarching policy on switching between biosimilars).

Any new medicine which receives a positive TA recommendation from NICE between document iterations will be approved through local ICB processes and will be included in future pathway updates.

Anti-CGRP medicines and botulinum toxin type A for the prevention of migraines pathway

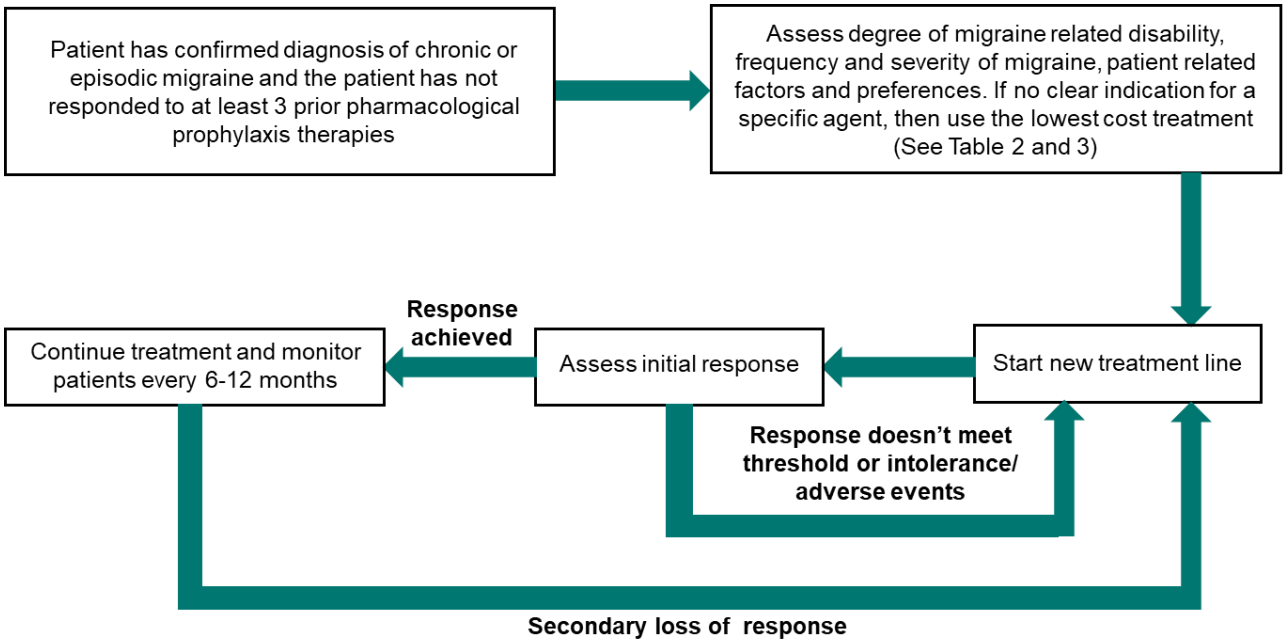

Table 1. Pathway definitions and actions

Description	Definition		Action
	Episodic Migraine (EM)	Chronic Migraine (CM)	
Type of migraine	Headache occurs on less than 15 days per month.	Headache occurs on at least 15 days per month (with features of migraine headache on at least 8 days per month) for more than 3 months.	Confirm patient has a diagnosis of EM or CM and has not responded to at least 3 prior pharmacological prophylaxis therapies and move on to next stage of the pathway.
Response achieved	Continuation criteria outlined in Table 3 is met.		Continue treatment and monitor patient every 6-12 months
Response does not meet threshold	After 12 weeks of treatment the frequency of migraine days* does not reduce by at least 50%. * *'migraine attacks' for rimegepant*	Anti-CGRP medicines - After 12 weeks of treatment the frequency of migraine days does not reduce by at least 30% Botulinum toxin type A - After 2 treatment cycles headache days does not reduce by at least 30%	Consider switching to a different anti-CGRP medicine (CM or EM) with a different mechanism of action or to botulinum toxin type A (CM only).
Secondary loss of response	Where the improvement meets initial thresholds, but this response is lost over time.		Consider changing to a new mode of action or alternative route of administration. Switch within class acceptable if loss of

		response is considered to be treatment specific.
Intolerance or adverse events	Where treatment is discontinued due to inability to tolerate side-effects of treatment.	Consider changing to a new mode of action or alternative route of administration.

Table 2. Drug treatment options. Individual agents within administration route listed in order of cost (lowest acquisition cost option by formulation highlighted)

Route of administration	Drug	EM	CM	Mode of action
Intramuscular injection	Botulinum toxin type A	✗	✓	Neurotoxin which inhibits release of acetylcholine
Oral	Rimegepant	✓	✗	Binds to receptor, inhibiting the ligand
	Atogepant	✓	✓	
Subcutaneous injection	Erenumab	✓	✓	
	Galcanezumab	✓	✓	Binds to CGRP ligand
	Fremanezumab	✓	✓	
Intravenous infusion	Eptinezumab	✓	✓	

Table 3. Anti-CGRP medicines and botulinum toxin type A dose, frequency, starting and continuation criteria for the prevention of migraines

Medicine (brand name)	Technology appraisal	Cost tier[1]	Dose and frequency	Starting criteria	Continuation criteria
Botulinum toxin type A[2] (Botox)	TA260 (2012)	Botox 100 unit – £138.20 per vial Botox 200 unit - £276.40 per vial	155–195 units, as 0.1 ml (5 units) injections to between 31 and 39 sites around the head and back of the neck.	• Headaches on at least 15 days per month of which ≥8 are days with migraine AND • At least 3 preventative medicines have not worked or are not tolerated or are unsuitable due to safety concerns AND • Condition is appropriately managed for medication overuse	• ≥30% reduction in headache days per month after 2 treatment cycles AND • type of migraine has not changed to episodic migraine for 3 consecutive months
Rimegepant (Vydura)	TA906 (2023)	£2,354 per year per patient	75mg every other day.	• At least 4 and fewer than 15 migraine attacks per month AND • At least 3 preventative medicines have not worked or are not tolerated or are unsuitable due to safety concerns	• ≥50% reduction in migraine attacks after 12 weeks
Atogepant (Qulipta)	TA973 (2024)	£2,376 per year per patient	60mg daily.	• ≥4 migraine days every month AND • At least 3 preventative medicines have not worked or are not tolerated or are	• EM – reduction of ≥50% migraine days after 12 weeks

[1] Drug acquisition cost only.

[2] Only the specific Botox brand by AbbVie Ltd is licensed for the prevention of chronic migraine.

Medicine (brand name)	Technology appraisal	Cost tier[1]	Dose and frequency	Starting criteria	Continuation criteria
				unsuitable due to safety concerns	• CM – reduction of ≥30% migraine days after 12 weeks
Erenumab (Aimovig)	TA682 (2021)	£	140mg or 70mg[3] dose every month.	• ≥4 migraine days every month AND • At least 3 preventative medicines have not worked or are not tolerated or are unsuitable due to safety concerns	• EM – reduction of ≥50% migraine days after 12 weeks • CM – reduction of ≥30% migraine days after 12 weeks
Galcanezumab (Emgality)	TA659 (2020)	££	240mg loading dose followed by a 120mg dose once a month.		
Fremanezumab (Ajovy)	TA764 (2022)	££	225 mg once a month, or 675 mg every 3 months (quarterly)		
Eptinezumab (Vyepti)	TA871 (2023)	£[4]	100 mg every 3 months.		

[3] 70mg dose of Erenumab is licensed, but it is not included under NICE TA guidance. SERMOG approved the use of this dosing schedule for the prevention of migraine as there maybe scenarios where specialists may deem it appropriate to use despite its lower efficacy than the 140mg dose. For example, where a patient achieves a response to the 140mg dose, but is unable to tolerate the side effects associated with the 140mg dose.

[4] Eptinezumab has additional associated costs including the administration as it is an intravenous infusion. It may also impact clinic capacity.

Version control:
Version 1.0 – Circulated to ICBs for ratification on 24th July 2025
Notes:
This policy recommendation will be reviewed when new information becomes available that is likely to have a material effect on the current recommendation. South East region ICBs will always consider appropriate individual funding requests (IFRs) through their IFR processes.