

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Doc ume	Pa ge	Lin e	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
	nt	No	No		· · · · · · · · · · · · · · · · · · ·
Medtronic	Adde ndu m	Ge ner al	Ge ner al	We would like to bring to your attention the recently published Clinical Commissioning Policy: Occipital Nerve Stimulation (ONS) for Adults with Intractable Chronic Migraines and Medically Refractory Chronic Cluster Headaches (NHS England D08/P/c). In which NHS England recommends the treatment of ONS for adults (18 years or over) who meet all the criteria in the commissioning policy. We politely ask that NICE take this treatment into consideration for the management of Chronic Migraines and Cluster Headaches in their recommendations to align guidance within the NHS. Thus ensuring clarity for health care professional and maximise adoption of all available interventions for maximum patient benefit and outcomes.	Thank you. Occipital nerve stimulation is outside the scope of the current update, which had a narrow remit limited to pharmacological preventative treatments for migraine. However, we have passed your comments to the surveillance team at NICE (who regularly review guidelines for update) for consideration when the guideline is next reviewed.
NHS England	Gene ral	Ge ner al	Ge ner al	No comments	Thank you
Royal College of Paediatrics and Child Health	Gene ral	Ge ner al	Ge ner al	No comments	Thank you
Department of Health	Gene ral	Ge ner al	Ge ner al	No comments	Thank you
Royal College of General	Short	Ge ner al	Ge ner al	The guidelines contain no specific changes that will effect GPs or problems with implementation. The inclusion of amitriptyline is welcome but will have no impact on practice.	Thank you



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Practitioners					
British Medical Association	Short	gen eral	gen eral	Where recommendations are made for off-license use of drugs NICE should request that the Secretary of State applies for a license for use in the specified circumstance in order to provide increased medico-legal protection for prescribers, should the planned legislation be enacted to enable this action.	Thank you for your comment. Where a medicine is being used outside of the marketing authorisation either as an off-label use or for an unlicensed indication this is highlighted in the guideline. The licensing of medicines is unfortunately outside of the role of NICE as licensing of medicines falls under the remit of the Medicines and Healthcare products Regulatory Agency (MHRA) and the European Medicines Agency (EMA). NICE has processes for updating guideline recommendations should a change in legislation lead to this action being required in future.
The Migraine Trust	Short	Ge ner al	Ge ner al	We welcome the updating of this evidence and patients will be reassured that NICE regularly and rigorously review the evidence for the treatment of primary headache conditions.	Thank you
British Society of Neuroradiolo gists	Short	3	21	Fully agree with this recommendation "Do not refer people diagnosed with tension-type headache, migraine, 21 cluster headache or medication overuse headache for neuroimaging solely 22 for reassurance. [1.3.3] [2012]" It is also the statement that is provided by the Royal College of Radiologists in their imaging guidelines.	Thank you. Please note however that the recommendation that you refer to did not form part of the current update and was made as part of the original NICE guideline on headaches in 2012.
British Medical Association	Short	4	17	We support this recommendation.	Thank you
Neonatal and paediatric Pharmacists Group	Short	5	1-4	We agree with this important amendment regarding topiramate use in women and girls of childbearing potential.	Thank you



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Neonatal and Paediatric Pharmacists Group	Short	5	4	We agree with this important amendment regarding topiramate use in women and girls of childbearing potential.	Thank you
British Society of Neuroradiolo gists	Short	6 and 7	1- 2 on pag e 7	Fully agree with the stated "red flags" that should necessitate imaging. It might be appropriate/useful to provide guidance on the type of imaging modality that would be most appropriate and the time interval that would be considered necessary. For instance acute severe headache requires urgent CT scanning to exclude subarachnoid haemorrhage; postural or cough headache requires MR scanning within the diagnostic target limits.	Thank you. Imaging is outside the scope of the current update, which had a narrow remit limited to pharmacological preventative treatments for migraine. However, NICE regularly reviews its guidance to decide if it needs to be updated, and so imaging could be considered for future update if new evidence becomes available in this area.
British Medical Association	Short	13	22	We support this recommendation.	Thank you
Neonatal and paediatric Pharmacists Group	Short	P 13 An d p14	24 Lin es 1-4	As above	Thank you
British Medical Association	Short	14	5	We support this recommendation.	Thank you
The Migraine Trust	Short	14	5	We are pleased to see that amitriptyline has been included in the updated evidence as many migraine patients have said that they have found this medication effective	Thank you
British Medical	Short	14	7	We support this recommendation.	Thank you



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Association					
Allergan	Short	14	10	Allergan is both disappointed and concerned that there is no reference to the use of botulinum toxin A as a possible treatment for preventing headaches in some adults with chronic migraine. Since the original guideline was published, NICE has reviewed Allergan's BOTOX® for treating chronic migraine in a separate health technology assessment (TA260) and has concluded that it should be recommended in specified circumstances. We believe that it is only right that this recommendation should be carried through into the Institute's own clinical guidelines where it is clearly relevant. For NICE to ignore its own recommendation for a particular treatment in one of its clinical guidelines would be both illogical and inconsistent and would, in our view, call into question the credibility of the guidelines themselves. This is especially the case where the guidelines have been updated to include treatments, including, for example, acupuncture that have not been subjected to the scrutiny of an HTA. We would also like to point out that further evidence demonstrating the real-world effect of using BOTOX® in the treatment of chronic migraine, and which was not available at the time of the HTA, has now been published and again it is disappointing that these have been overlooked in evidence-based guidelines.	Thank you. Botulinum toxin A was not included in the current update because of the existing NICE technology appraisal in this area. This appraisal (TA260) still stands and is included in the NICE headaches pathway (http://pathways.nice.org.uk/pathways/headaches). There is also a cross reference to the technology appraisal in the short version of the guidance. We have now also added a cross reference to the technology appraisal in the addendum to the guideline that was produced as part of the guideline update. Note that acupuncture was not included as part of the guideline update; the update was limited to pharmacological treatments for the prevention of migraine.
Neonatal	Short	13		We agree with this important amendment regarding topiramate	Thank you



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and		14	1	use in women and girls of childbearing potential.	
Paediatric			4		
Pharmacists					
Group					