

National Institute for Health and Care Excellence

IP1293/2 Transcutaneous electrical stimulation of the supraorbital nerve for treating and preventing migraine

IPAC date: 11 August 2022

Com . no.	Consultee name and organisation	Sec. no.	Comments	Response
1	Consultee 1 The Migraine Trust	General	The option to use a non-drug acute treatment is welcomed. Having non-drug options is important for people with migraine.	Please respond to all comments Thank you for your comments.
2	Consultee 1 The Migraine Trust	1	We agree that with limited evidence, special arrangements and audit will be crucial to understand the usefulness of this treatment so that people affected by migraine can make an informed choice with their doctor in selecting the treatment option and to also understand who would benefit most.	Thank you for your comments and agreeing with the recommendation.

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3	Consultee 1 The Migraine Trust	General	It would also be important to list who might have contraindications or be unsuitable for this treatment. For example, would it be safe in people with implants, epilepsy, previous head surgery and pregnancy?	Thank you for your comments. The contraindications or who might be suitable for this treatment are contained in the manufacturers IFU of the device currently available for this procedure. Please refer to the device manual 34077 - Manuel Cefaly Dual - V04 - EN 04 - 16.07.2019.pdf Our guidance contains an overview of the evidence.
4	Consultee 1 The Migraine Trust	General	Can it be used with more rare types of migraine such as hemiplegic migraine and migraine with brain stem aura?	Thank you for your comments. The guidance covers treatment and prevention of episodic and chronic migraine. The indications for this treatment are contained in the manufacturers IFU of the device currently available for this procedure. Please refer to the device manual 34077 - Manuel Cefaly Dual - V04 - EN 04 - 16.07.2019.pdf and consult with the manufacturer for further advice.

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5	Consultee 1 The Migraine Trust	General	How long should it be used to determine effectiveness? What are the potential side effects users should be aware of? Will there be dosing instructions and limits?	<p>Thank you for your comments.</p> <p>Please refer to the procedure description in section 2.4 and 2.5 in the guidance. 2.5 states that stimulation is applied daily for about 1 to 2 hours during an acute migraine attack, and for 20 minutes for prevention between attacks.</p> <p>Section 3.3 in the guidance lists the key safety outcomes considered by the professional experts and the committee.</p> <p>Also, please refer to directions for use and the listed side effects in the device manual (for the device currently available for this procedure) 34077 - Manuel Cefaly Dual - V04 - EN 04 - 16.07.2019.pdf</p>
6	Consultee 1 The Migraine Trust	General	Will NICE review the evidence after an interim period of use? This would help people with migraine to make an informed choice on whether they should see their doctor for a referral to the specialist to access the device.	<p>Thank you for your comments.</p> <p>Evidence from peer reviewed publications has been considered in the overview. When substantial new evidence is published NICE will review the guidance. The stakeholder or organisation can alert or contact NICE about significant new evidence.</p>
7	Consultee 1 The Migraine Trust	General	Can people affected by migraine see a specialist nurse to be assessed and prescribed the device and so reduce the waiting time to see the Neurologist at the headache clinic?	<p>Thank you for your comments.</p> <p>Section 1.4 in the guidance has been amended to state that <i>'patient selection should usually be done by clinicians (including clinical nurse specialists) with expertise in the management of migraine'</i>.</p>

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8	Consultee 1 The Migraine Trust	General	Will NICE review NHS access of other devices such as sTMS and gammaCore, for which there is more evidence for use in migraine?	Please respond to all comments Thank you for your comments. When substantial new evidence is published NICE will review other guidance on migraine (IPG552, IPG477). Please see list of relevant NICE guidance section in the overview which includes MTG 46 on gammaCore. https://www.nice.org.uk/guidance/mtg46

"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."