

# NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

## Medical technology guidance

### SCOPE

#### gammaCore for cluster headache

## 1 Technology

### 1.1 *Description of the technology*

gammaCore (electroCore) is a handheld, patient-controlled, non-invasive vagus nerve stimulator used for treating and preventing cluster headaches. The patient holds the device to their neck (over the cervical branch of the vagus nerve) and uses it to deliver a small electric current for about 2 minutes. The aim of treatment is to modify pain signals by stimulating the vagus nerve through the skin of the neck. gammaCore can be used acutely when the person feels a cluster headache beginning or daily to help prevent cluster headaches. The device is small and portable and, after brief training, is designed to be used anywhere that is convenient.

NICE has published a [Medtech innovation briefing](#) on this technology.

### 1.2 *Regulatory status*

gammaCore received a CE mark as a class IIa device in August 2011 for primary headache (migraine, cluster headache and hemicrania continua) and medication overuse headache in adults. This evaluation focusses on its use for treating and preventing cluster headaches after standard care options have been unsuccessfully tried.

### 1.3 *Claimed benefits*

The benefits to patients claimed by the company are:

- Reduces the frequency, duration and severity of cluster headache attacks, when used preventatively

Medical technology scope: gammaCore for treating cluster headache

February 2019

© NICE 2018. All rights reserved. Subject to [Notice of rights](#).

Page 1 of 8

- Improves quality of life
- Therapy is safe, non-pharmacological, and non-invasive, there are no contraindications with other medicines
- Daily therapy is not limited, unlike other treatments
- Can be self-administered in almost any setting; home, office, etc.

The benefits to the healthcare system claimed by the company are:

- Reduces the use of expensive medication with associated reduction in electrocardiogram and blood monitoring required when prescribing verapamil and lithium carbonate (reduction in primary care and outpatient appointments)
- No contraindications to other pharmacological therapies
- Can prevent last-resort costly surgical procedures (invasive neuromodulation).
- Empowers patients to self-care at home and manage their condition themselves, away from a healthcare service
- Provides an additional, licenced treatment option for healthcare professionals treating cluster headache.

#### **1.4      *Relevant diseases and conditions***

Around 1-2 people in 1,000 in the UK experience cluster headache. The company estimate that in about 5% of people with cluster headache, standard care will not work or be unsuitable. Expert advice suggests that 5% may be an under estimate because some people only receive a partial benefit from standard care treatments.

#### **1.5      *Current management***

NICE's clinical guideline on [headache](#) states that oxygen or subcutaneous or nasal spray triptans should be offered for acute treatment of cluster headache. The guideline states that paracetamol, NSAIDS, opioids, ergots or oral triptans should not be offered for the acute treatment of cluster headache as they are not effective.

The guideline recommends that verapamil is offered for long-term prophylaxis and that electrocardiogram monitoring should be offered to patients receiving verapamil. Oral steroids (such as prednisolone) may also be prescribed on their own or alongside verapamil but can only be used for a short time due to side effects. Anticonvulsants and lithium carbonate may also be offered. Lithium carbonate requires close monitoring through blood tests to avoid toxicity. The use of verapamil, anticonvulsants and lithium carbonate for cluster headache is outside their marketing authorisations.

Current NHS practice also includes offering additional or alternative treatment options when first-line treatments are ineffective or not tolerated. These include invasive treatments such as surgically implanted sphenopalatine ganglion nerve stimulators, deep brain stimulation (which requires neurosurgery), occipital nerve block injections. Intravenous dihydroergotamine (unlicensed) which clinical experts have stated is available at specialist centres to a small number of people, in whom verapamil and anticonvulsants are ineffective. This treatment requires a 5-day inpatient stay.

NICE interventional procedures guidance on [transcutaneous stimulation of the cervical branch of the vagus nerve for cluster headache and migraine](#) (2016) recommends that the procedure should only be used with special arrangements for clinical governance, consent and audit or research.

Expert advice has stated that many people with cluster headache do not get enough pain relief with current treatment options, which are often limited by side effects and contraindications.

gammaCore is intended for use by people with cluster headache for whom standard treatment has been unsuccessful or in people who cannot have other prescribed treatments. If used, it is most likely to be an option before more invasive procedures or treatments with serious side effects are considered. gammaCore is most likely to be prescribed by clinicians who specialise in headache management such as neurologists and pain specialists. People using gammaCore will need brief training which is provided

by the company at no extra cost. Once trained, people with cluster headache can use gammaCore in any setting.

## 2 Statement of the decision problem

	<b>Final scope issued by NICE</b>
Population	People over the age of 18 with cluster headache for whom standard care is ineffective or contraindicated.
Intervention	gammaCore
Comparator(s)	<ul style="list-style-type: none"> <li>• Subcutaneous or nasal spray triptan therapy (acute)</li> <li>• Oxygen therapy (at home), used alone or alongside subcutaneous or nasal spray triptan therapy (acute)</li> <li>• Verapamil (preventative)</li> <li>• Sphenopalatine ganglion nerve stimulators (acute and preventative treatment for chronic cluster headache)</li> <li>• Occipital nerve block (preventative)</li> </ul>
Outcomes	<p>The outcome measures to consider include:</p> <ul style="list-style-type: none"> <li>• Frequency, severity and duration of acute episodes of cluster headache</li> <li>• Time taken to relieve pain of acute episode (acute use)</li> <li>• Average response rate and proportion of patients at 50% and 75% response rate</li> <li>• Number of times device used for daily prevention</li> <li>• Number of times device used for acute treatment</li> <li>• Patient reported pain and disability scores</li> <li>• Patient health-related quality of life, including impact on occupation and employment</li> <li>• Patient satisfaction</li> <li>• Reduction of ECG and blood testing for monitoring of drug treatments</li> <li>• Use of outpatient and healthcare services, including psychiatric care</li> <li>• device-related adverse events.</li> </ul>
Cost analysis	<p>Costs will be considered from an NHS and personal social services perspective.</p> <p>The time horizon for the cost analysis will be sufficiently long to reflect any differences in costs and consequences between the technologies being compared.</p> <p>Sensitivity analysis will be undertaken to address uncertainties in the model parameters, which will include scenarios in which different numbers and combinations of devices are needed.</p>
Subgroups to be considered	<ul style="list-style-type: none"> <li>• Acute treatment of cluster headache</li> <li>• Prevention of cluster headache</li> <li>• Episodic cluster headache</li> <li>• Chronic cluster headache</li> </ul>

Special considerations, including those related to equality	People with cluster headache are likely to be described as disabled because it is a chronic condition which is likely to last longer than 1 year. This technology has the potential to avoid invasive treatments (such as sphenopalatine ganglion nerve stimulation implants), or avoid the use of unlicensed medications with potentially serious side effects.	
Special considerations, specifically related to equality issues	Self-administration of treatment with gammaCore needs manual dexterity and the ability to follow instructions. gammaCore cannot be used by people with cochlear implants or pacemakers and has not been used in people who are pregnant, lactating or aged under 18 years.	
	Are there any people with a protected characteristic for whom this device has a particularly disadvantageous impact or for whom this device will have a disproportionate impact on daily living, compared with people without that protected characteristics?	Yes
	Are there any changes that need to be considered in the scope to eliminate unlawful discrimination and to promote equality?	No
	Is there anything specific that needs to be done now to ensure MTAC will have relevant information to consider equality issues when developing guidance?	No
	The committee will need to consider that gammaCore cannot be used by people included in the above statement.	

### 3 Related NICE guidance

#### Published

- Transcutaneous stimulation of the cervical branch of the vagus nerve for cluster headache and migraine. NICE interventional procedure guidance 552 (2016). Available from [www.nice.org.uk/guidance/IPG552](http://www.nice.org.uk/guidance/IPG552)
- Headaches in over 12s: diagnosis and management. NICE clinical guideline 150 (2012, updated 2015). Available from [www.nice.org.uk/guidance/CG150](http://www.nice.org.uk/guidance/CG150)
- Implantation of a sphenopalatine ganglion stimulation device for chronic cluster headache. NICE interventional procedure guidance 527 (2015). Available from [www.nice.org.uk/guidance/IPG527](http://www.nice.org.uk/guidance/IPG527)

#### Under development

- None identified

## **4 External organisations**

### **4.1 Professional organisations**

#### **4.1.1 Professional organisations invited to comment on the draft scope**

The following societies have been alerted to the availability of the draft scope for comment:

- Association of British Neurologists
- Association of Neuroscience Nurses
- Brain Research UK
- British Association for the Study of Headache
- British Pain Society
- Royal College of Anaesthetists
- Royal College of General Practitioners
- Royal College of Nursing
- Royal College of Physicians
- Society of British Neurological Surgeons

### **4.2 Patient organisations**

At the selection stage, NICE's Public Involvement Programme contacted the following organisations for patient commentary and alerted them to the availability of the draft scope for comment:

- Migraine Trust
- OUCH UK
- Pain Concern
- Pain Relief Foundation
- Pain UK
- The Brain Charity