

## NHS West Lancashire CCG

### Policies for the Commissioning of Healthcare

#### Non-invasive Vagus Nerve Stimulation (gammaCore™) in headache Policy

	<b>Introduction</b>
	This document is part of a suite of policies that the CCG uses to drive its commissioning of healthcare. Each policy in that suite is a separate public document in its own right but will be applied with reference to other policies in that suite.
<b>1</b>	<b>Policy</b>
<b>1.1</b>	The CCG will only commission the use of non-invasive vagus nerve stimulation (nVNS) to treat cluster headache in patients with refractory episodic or chronic cluster headache <sup>1,2</sup> when all of the following criteria are satisfied:
<b>1.1.1</b>	<ul style="list-style-type: none"> <li>• The treatment is initiated by a clinician specialising in the treatment of refractory headaches AND</li> </ul>
<b>1.1.2</b>	<ul style="list-style-type: none"> <li>• The patient has undergone an initial 3-month period of treatment at no cost to the commissioner AND</li> </ul>
<b>1.1.3</b>	<ul style="list-style-type: none"> <li>• The initial 3-month period of treatment resulted in a significant reduction in symptoms as recorded in a headache diary.</li> </ul>
<b>1.2</b>	The CCG will not routinely commission the use of nVNS in the management of patients with migraine <sup>1,3</sup> as it considers the use of nVNS in this indication does not accord with the Principles of Effectiveness and Cost-Effectiveness.
<b>2</b>	<b>Scope and definitions</b>
<b>2.1</b>	This policy is based on the CCGs Statement of Principles for Commissioning of Healthcare (version in force on the date on which this policy is adopted).
<b>2.2</b>	nVNS are used for a wide range of indications. For the purpose of this policy nVNS refers to a non-implantable hand-held stimulator whose objective is to prevent or treat headaches.
<b>2.3</b>	The scope of this policy includes requests for nVNS for patients over the age of 18 years.
<b>2.4</b>	The CCG recognises that a patient may have certain features, such as <ul style="list-style-type: none"> <li>• having a headache condition;</li> </ul>

	<ul style="list-style-type: none"> <li>• wishing to have a service provided for their headache condition;</li> <li>• being advised that they are clinically suitable for nVNS, and</li> <li>• be distressed by their headache condition, and by the fact that that they may not meet the criteria specified in this commissioning policy.</li> </ul> <p>Such features place the patient within the group to whom this policy applies and do not make them exceptions to it.</p>
<b>2.6</b>	For the purpose of this policy the CCG defines refractory as persisting despite trying a number or combination of pharmacological therapies at sufficient doses for sufficient time and when the patient is measurably disabled by the condition.
<b>2.7</b>	This policy reflects NICE guidance gammaCore for cluster headache. MedTech Guidance (MTG) 46. <a href="https://www.nice.org.uk/guidance/mtg46">https://www.nice.org.uk/guidance/mtg46</a>
<b>3</b>	<b>Appropriate Healthcare</b>
<b>3.1</b>	The purpose of using nVNS stimulation is normally to either prevent headache attacks in patients with chronic/episodic headaches or to disrupt pain signals during an attack, reducing the symptoms experienced.
<b>3.2</b>	The CCG regards the achievement of this purpose as according with the Principle of Appropriateness. Therefore, this policy does not rely on the Principle of Appropriateness. Nevertheless, if a patient is considered exceptional in relation to the principles on which the policy does rely, the CCG may consider the principle of appropriateness in the particular circumstances of the patient in question when considering an application to provide funding.
<b>4</b>	<b>Effective Healthcare</b>
<b>4.1</b>	The policy criteria relating to the use of nVNS for the management of migraine relies on the Principle of Effectiveness as the CCG considers there is insufficient evidence to demonstrate it is effective in preventing migraine occurrence or reducing the symptoms of attacks.
<b>5</b>	<b>Cost Effectiveness</b>
<b>5.1</b>	<p>The policy criteria relating to the use of nVNS for the management of migraine relies on the Principles of Cost-Effectiveness.</p> <p>Nevertheless if a patient is considered exceptional in relation to the principles on which the policy does rely, the CCG may consider whether the purpose of the treatment is likely to be achieved in this patient without undue adverse effects when considering an application to provide funding.</p>
<b>6</b>	<b>Ethics</b>

<b>6.1</b>	The CCG does not call into question the ethics of nVNS for the management of headaches and therefore this policy does not rely on the Principle of Ethics. Nevertheless, if a patient is considered exceptional in relation to the principles on which the policy does rely, the CCG may consider whether the treatment is likely to raise ethical concerns in this patient when considering an application to provide funding.
<b>7</b>	<b>Affordability</b>
<b>7.1</b>	The CCG does not call into question the affordability of nVNS for the management of headaches and therefore this policy does not rely on the Principle of Affordability. Nevertheless, if a patient is considered exceptional in relation to the principles on which the policy does rely, the CCG may consider whether the treatment is likely to be affordable in this patient when considering an application to provide funding.
<b>8</b>	<b>Exceptions</b>
<b>8.1</b>	The CCG will consider exceptions to this policy in accordance with the Policy for Considering Applications for Exceptionality to Commissioning Policies.
<b>8.2</b>	In the event of inconsistency, this policy will take precedence over any non-mandatory NICE guidance in driving decisions of this CCG. A circumstance in which a patient satisfies NICE guidance but does not satisfy the criteria in this policy does not amount to exceptionality.
<b>9</b>	<b>Force</b>
<b>9.1</b>	This policy remains in force until it is superseded by a revised policy or by mandatory NICE guidance relating to this intervention, or to alternative treatments for the same condition.
<b>9.2</b>	<p>In the event of NICE guidance referenced in this policy being superseded by new NICE guidance, then:</p> <ul style="list-style-type: none"> <li>• If the new NICE guidance has mandatory status, then that NICE guidance will supersede this policy with effect from the date on which it becomes mandatory.</li> <li>• If the new NICE guidance does not have mandatory status, then the CCG will aspire to review and update this policy accordingly. However, until the CCG adopts a revised policy, this policy will remain in force and any references in it to NICE guidance will remain valid as far as the decisions of this CCG are concerned.</li> </ul>
<b>10</b>	<b>References</b>

	<p><sup>1</sup>NICE Interventional procedures guidance (IPG) 552 Transcutaneous stimulation of the cervical branch of the vagus nerve for cluster headache and migraine. Published March 2016. <a href="https://www.nice.org.uk/guidance/ipg552">https://www.nice.org.uk/guidance/ipg552</a></p> <p><sup>2</sup> NICE MedTech Guidance (MTG) 46 gammaCore for cluster headache. Published December 2019 <a href="https://www.nice.org.uk/guidance/mtg46">https://www.nice.org.uk/guidance/mtg46</a></p> <p><sup>3</sup> Diener HC, Goadsby PJ, Ashina M <i>et al.</i> Non-invasive vagus nerve stimulation (nVNS) for the preventive treatment of episodic migraine: The multicentre, double-blind, randomised, sham-controlled PREMIUM trial. Cephalalgia Sep 2019; p. 333102419876920  <a href="https://journals.sagepub.com/doi/pdf/10.1177/0333102419876920">https://journals.sagepub.com/doi/pdf/10.1177/0333102419876920</a></p>
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### Appendix 1: Associated OPCS codes

The codes applicable to this policy are:

<b>OPCS codes</b>
None identified
<b>ICD 10 Diagnosis code</b>
G44.0 cluster headache

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