

Policy for Non-invasive Vagus Nerve Stimulation (gammaCore™) in Headache

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Version:	1.2
Purpose	This document is part of a suite of policies that the Integrated Care Board (ICB) 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.
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Author (inc Job Title):	
Ratified by: (Name of responsible Committee)	ICB Board (Adopted 1 July 2022)
Cross reference to other Policies/Guidance	
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Target audience:	All LSCICB staff

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Document control:		
Date:	Version Number:	Section and Description of Change
January 2020	V0.1	First draft policy done.
February 2020	V0.2	Scope of the policy restricted to migraine only, following indication that commissioning responsibility for cluster headache will remain with NHSE. Scope clarified to patients over the age of 18 years, in line with supplier marketing/evidence base.
November 2020	V0.3	Scope changed back to include cluster headaches as commissioning responsibility transfers to CCGs on 1 April 2021
May 2021	V1.0	Ratified by Strategic Commissioning Committee.
May 2021	V1.1	Word order in title changed. OPCS Codes added.
July 2022	V1.2	Policy adopted by Lancashire and South Cumbria ICB – references to CCG replaced by ICB where relevant

1. Policy

- 1.1 The ICB 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 when all of the following criteria are satisfied:
 - 1.1.1 The treatment is initiated by a clinician specialising in the treatment of refractory headaches AND
 - 1.1.2 The patient has undergone an initial 3-month period of treatment at no cost to the commissioner AND
 - 1.1.3 The initial 3-month period of treatment resulted in a significant reduction in symptoms as recorded in a headache diary.
- 1.2 The ICB will not routinely commission the use of nVNS in the management of patients with migraine as it considers the use of nVNS in this indication does not accord with the Principles of Effectiveness and Cost-Effectiveness.

2. Scope and definitions

- 2.1 This policy is based on the ICB's Statement of Principles for Commissioning of Healthcare (version in force on the date on which this policy is adopted).
- 2.2 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.
- 2.3 The scope of this policy includes requests for nVNS for patients over the age of 18 years.
- 2.4 The ICB recognises that a patient may have certain features, such as:
 - having a headache condition
 - wishing to have a service provided for their headache condition
 - being advised that they are clinically suitable for nVNS; and
 - be distressed by their headache condition, and by the fact that they may not meet the criteria specified in this commissioning policy.

Such features place the patient within the group to whom this policy applies and do not make them exceptions to it.

- 2.5 For the purpose of this policy the ICB 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.
- 2.6 This policy reflects NICE guidance gammaCore for cluster headache. MedTech Guidance (MTG) 46. <https://www.nice.org.uk/guidance/mtg46>

3. Appropriate Healthcare

- 3.1 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.
- 3.2 The ICB 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 ICB may consider the principle of appropriateness in the particular circumstances of the patient in question when considering an application to provide funding.

4. Effective Healthcare

- 4.1 The policy criteria relating to the use of nVNS for the management of migraine relies on the Principle of Effectiveness as the ICB considers there is insufficient evidence to demonstrate it is effective in preventing migraine occurrence or reducing the symptoms of attacks.

5. Cost Effectiveness

- 5.1 The policy criteria relating to the use of nVNS for the management of migraine relies on the Principles of Cost-Effectiveness.
- 5.2 Nevertheless, if a patient is considered exceptional in relation to the principles on which the policy does rely, the ICB 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.

6. Ethics

- 6.1 The ICB 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 ICB may consider whether the treatment is likely to raise ethical concerns in this patient when considering an application to provide funding.

7. Affordability

- 7.1 The ICB 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 ICB may consider whether the treatment is likely to be affordable in this patient when considering an application to provide funding.

8. Exceptions

- 8.1 The ICB will consider exceptions to this policy in accordance with the Policy for Considering Applications for Exceptionality to Commissioning Policies.

8.2 In the event of inconsistency, this policy will take precedence over any non-mandatory NICE guidance in driving decisions of this ICB. A circumstance in which a patient satisfies NICE guidance but does not satisfy the criteria in this policy does not amount to exceptionality.

9. Force

9.1 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.

9.2 In the event of NICE guidance referenced in this policy being superseded by new NICE guidance, then:

- 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.
- If the new NICE guidance does not have mandatory status, then the ICB will aspire to review and update this policy accordingly. However, until the ICB 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 ICB are concerned.

10. References

NICE Interventional procedures guidance (IPG) 552 Transcutaneous stimulation of the cervical branch of the vagus nerve for cluster headache and migraine. Published March 2016. <https://www.nice.org.uk/guidance/ipg552>

NICE MedTech Guidance (MTG) 46 gammaCore for cluster headache. Published December 2019 <https://www.nice.org.uk/guidance/mtg46>

Diener HC, Goadsby PJ, Ashina M et al. 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 <https://journals.sagepub.com/doi/pdf/10.1177/0333102419876920>

11. Associated OPCS codes

OPCS codes
None identified
ICD 10 Diagnosis code
G44.0 cluster headache