NHS
Commissioning Board

Clinical Commissioning Policy: Vagal Nerve Stimulation for Epilepsy

April 2013

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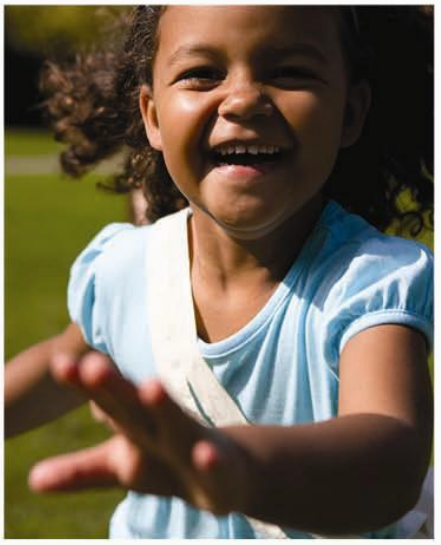

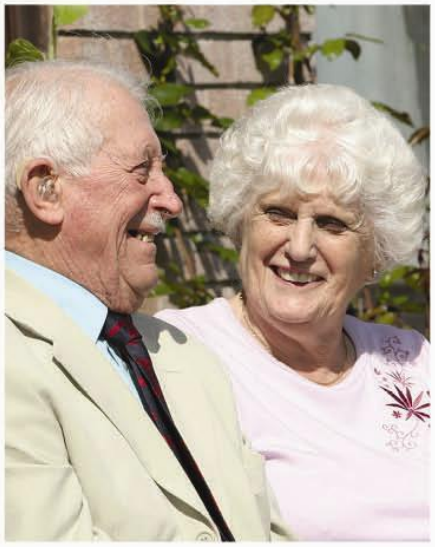

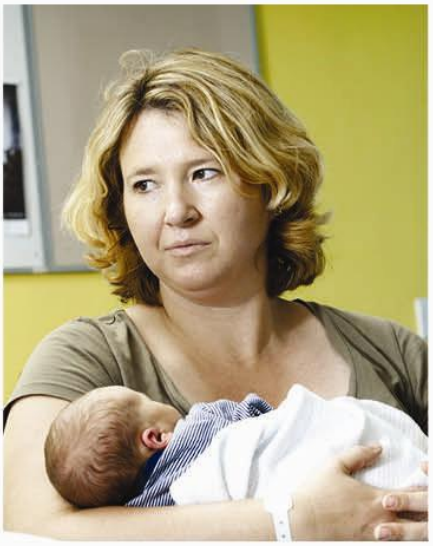

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NHS Commissioning Board

Clinical Commissioning Policy: Vagal Nerve Stimulation for Epilepsy

First published: April 2013

Prepared by the NHS Commissioning Board Clinical Reference Group for Neurosciences

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Contents

Policy Statement

The NHS Commissioning Board (NHS CB) will commission Vagal Nerve Stimulation for epilepsy in accordance with the criteria outlined in this document.

In creating this policy the NHS CB has reviewed this clinical condition and the options for its treatment. It has considered the place of this treatment in current clinical practice, whether scientific research has shown the treatment to be of benefit to patients, (including how any benefit is balanced against possible risks) and whether its use represents the best use of NHS resources.

This policy document outlines the arrangements for funding of this treatment for the population in England.

Equality Statement

The NHS CB has a duty to have regard to the need to reduce health inequalities in access to health services and health outcomes achieved as enshrined in the Health and Social Care Act 2012.The NHS CB is committed to ensuring equality of access and non-discrimination, irrespective of age, gender, disability (including learning disability), gender reassignment, marriage and civil partnership, pregnancy and maternity, race, religion or belief, sex (gender) or sexual orientation. In carrying out its functions, the NHS CB will have due regard to the different needs of protected equality groups, in line with the Equality Act 2010. This document is compliant with the NHS Constitution and the Human Rights Act 1998. This applies to all activities for which they are responsible, including policy development, review and implementation

Plain Language Summary

Epilepsy is a neurological condition characterised by recurrent epileptic seizures unprovoked by any immediately identifiable cause. Epilepsy affects a large number of people. Patients with epilepsy that cannot be managed with conventional treatments require more out-patient clinic time, combination therapy (often with newer, expensive anti-epileptic drugs) and hospitalisation.

Vagus Nerve Stimulation (VNS) is a treatment that has been shown to reduce the frequency of seizures in selected patients, both adults and children, whose epilepsy has not been controlled by medication and who are not suitable for surgery to manage their epilepsy.

Information on the outcome of treatments for these patients will be collected and considered when this policy is reviewed.

1. Introduction

NICE Clinical Practice Guideline for the management of the epilepsies[1] states that Vagal Nerve Stimulation (VNS) is indicated for use as an adjunctive therapy for refractory epilepsy in children, young people and adults.

Epilepsy affects a large number of people. Patients with refractory epilepsy require more out-patient clinic time, combination therapy (often with newer, expensive anti- epileptic drugs) and hospitalisation.[2]

Optimal management improves health outcomes and can also help to minimise other, often detrimental, impacts on social, educational and employment activity. The NICE Clinical Guideline for Epilepsies (CG20) stated that the annual estimated cost of established epilepsies was £2 billion (direct and indirect costs).[1]

2. Definitions

Epilepsy

Epilepsy is a neurological condition characterised by recurrent epileptic seizures unprovoked by any immediately identifiable cause. An epileptic seizure is the clinical manifestation of an abnormal and excessive discharge of a set of neurons in the brain.[2]

Vagal Nerve Stimulation (VNS)

VNS involves implantation of a battery-powered pulse generator under the skin usually of the upper left chest. A wire tunnelled under the skin is connected to the left vagus nerve. Parameters (such as pulse width and frequency, current intensity and on/off cycles) can be programmed into the pulse generator using a programming wand. At any time additional stimulation can be applied or the device turned off. The battery is sufficient for about 3 to 8 years (median life is 5-6 yrs) and can be replaced under local anaesthesia.[2]

3. Aim and objectives

To outline the criteria under which VNS is commissioned by the NHS CB for children, young people and adults.

4. Criteria for commissioning

VNS is commissioned for adults and children who meet all the criteria in either section A or B as indicated below, as appropriate to their clinical circumstances.

Patient criteria which would exclude treatment according to this policy are also listed below in section C.

A. Medically Refractory Focal-Onset Seizures

The patient has medically refractory focal-onset seizures. Medically refractory means seizures that occur in spite of therapeutic levels of anti-epileptic drugs or seizures that cannot be treated with therapeutic levels of anti-epileptic drugs because of intolerable adverse side effects.

AND

The patient has failed or is not eligible for resective surgery

AND

At least 2 complex partial seizures per month OR recurrent life threatening status epilepticus

3 first line anti-epileptic drugs have been tried over a period of at least 2 years

B. Medically Refractory Generalised Seizures

The patient has medically refractory generalised seizures. Medically refractory means seizures that occur in spite of therapeutic levels of anti-epileptic drugs or seizures that cannot be treated with therapeutic levels of anti-epileptic drugs because of intolerable adverse side effects.

AND

The patient has failed or is not suitable for resective surgery

AND

At least 1 generalised seizure per month OR recurrent life threatening status epilepticus

3 first line anti-epileptic drugs have been tried over a period of at least 2 years

C. Exclusion criteria

The following criteria will exclude a patient from approval for VNS

- For treatment of patients with seizures other than focal-onset seizures or medically refractory generalised seizures
- For patients who can be treated successfully with anti-epileptic drugs and / or ketogenic diet
- For treatment of patients with depression in isolation
- For the treatment of essential tremor in isolation
- For the treatment of headaches in isolation
- For the treatment of obesity in isolation

5. Patient pathway

The proposed treatment must have been approved by an epilepsy MDT whose core membership will include:

A neurosurgeon with specific competence in epilepsy surgery

A physician with appropriate competencies

An epilepsy specialist nurse

With support as required from:

A psychologist

A second physician with appropriate competencies

6. Governance arrangements

VNS should only be performed in an experienced specialist centre willing to publish its results and use established clinically relevant patient outcomes.

7. Epidemiology and needs assessment

Epilepsy is a common neurological disorder characterised by recurring seizures. Different types of epilepsy have different causes. Epilepsy can be classified based on the origin of seizure. Seizures which begin simultaneously in both hemispheres are called generalised and when the seizure begins in one or more localised foci they are referred to as partial (or focal).[2]

Accurate estimates of incidence and prevalence are difficult to achieve because identifying people who may have epilepsy is difficult. Epilepsy has been estimated to affect between 362,000 and 415,000 people in England. In addition, there will be further individuals, estimated to be 5–30%, so amounting to up to another 124,500 people, who have been diagnosed with epilepsy, but in whom the diagnosis is incorrect. Incidence is estimated to be 50 per 100,000 per year and the prevalence of active epilepsy in the UK is estimated to be 5–10 cases per 1000. Two-thirds of people with active epilepsy have their epilepsy controlled satisfactorily with anti- epileptic drugs (AEDs).[1]
Other approaches may include surgery. In children a ketogenic diet (a high-fat, adequate- protein, low-carbohydrate diet) is sometimes used. According to an observational study in children and adult patients, approximately 30% of the population with epilepsy has inadequate control of seizures with AED.[2] An Australian Health Technology Assessment (HTA) report observed that only 1% of the population with epilepsy is suitable for resective surgery.[2]

8. Evidence base

NICE CG137, published 2012[1] updates and replaces NICE CG 20. New recommendations have been added for the pharmacological treatment of people with epilepsy, including the use of ketogenic diet.

VNS is indicated for use as an adjunctive therapy in reducing the frequency of seizures in adults who are refractory to antiepileptic medication but who are not suitable for resective surgery. This includes adults whose epileptic disorder is dominated by focal seizures (with or without secondary generalisation) or generalised seizures.[1]

VNS is indicated for use as an adjunctive therapy in reducing the frequency of seizures in children and young people who are refractory to antiepileptic medication but who are not suitable for resective surgery. This includes children and young people whose epileptic disorder is dominated by focal seizures (with or without secondary generalisation) or generalised seizures.[1]

Evidence suggests that with VNS >50% reduction in seizures can be achieved in 21-71% patients, with studies of long-term follow-up suggesting further reductions in seizures after 1 year, resulting in more than 1 in 3 patients experiencing >50% reduction in seizures. Reductions in seizure severity and improved quality of life also occur in patients with a less significant change in seizure frequency, often making continuation with VNS worthwhile. However, some patients do not respond to VNS, or may experience an increase in seizures. Unfortunately, the evidence available to date does not help predict those patients who will have the best outcomes.[3]

Evidence suggests that surgical complications are rare, and that the majority of side effects are minor, stimulation related and improve with time or a change in stimulation parameters. Overall rates of sudden unexpected deaths are similar to those for the normal refractory epilepsy population - they have been reported to be raised for the first 2 years after VNS and then less than half normal rates for subsequent years. There is no evidence of increased mortality in patients with VNS compared with uncontrolled epilepsy.[3]

Evidence on cost-effectiveness suggests that there are savings indirect medical costs following VNS that offset the cost of the procedure in approximately 3 years. The cost per Quality Adjusted Life Year (QALY) gained has been calculated as £4,785, assuming one response was obtained for every three implants (33%).[3]

9. Rationale behind the policy statement

Epilepsy affects a large number of people. Patients with refractory epilepsy require more out-patient clinic time, combination therapy (often with newer, expensive anti- epileptic drugs) and hospitalisation.

VNS is considered to be an effective option for patients who are refractory to antiepileptic medication, who are not suitable for resective surgery.

This policy outlines the NHS CB criteria for NHS funded VNS, ensuring equity of access for patients in England.

10. Mechanism for funding

From April 2013 the NHS CB will be responsible for commissioning in line with this policy on behalf of the population of England.

11. Audit requirements

Providers will be expected to provide information on activity and outcomes on request.

12. Documents which have informed this policy

See references

13. Links to other policies

The mechanism operated by the NHS CB for funding requests outside of the clinical criteria in this policy is yet to be finalised.

14. Date of review

2013/14

References

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2. West Midlands Specialised Commissioning Group Policy Vagal Nerve Stimulation (VNS) for treatment of Epilepsy. 2010.
3. Thames Valley Priorities Committees (Berkshire PCTs) Policy Statement 96: Vagus Nerve Stimulation (VNS) for refractory epilepsy in children and adults. 2006.
4. National Institute for Health and Clinical Excellence (NICE). Vagus nerve stimulation for refractory epilepsy in children. IPG50, 2004. Available from: http://www.nice.org.uk/Guidance/IPG050 . Accessed 20/08/2012.
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Change Notice for Published Specifications and Products

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Amendment **to the Published Products**

Product Name	Clinical Commissioning: Policy Vagal Nerve Stimulation
Ref No	D04/P/d
CRG	Neurosciences

Description of changes required

Describe what was stated in original document	Describe new text in the document	Section/Paragraph to which changes apply	Describe why document change required	Changes made by	Date change made
'Draft' watermark appears on the front page	No text changes in the policy, change is the removal of the 'Draft' watermark	Front page	This document is not draft	CRG	July 2013