



Clinical Commissioning Policy: Deep Brain Stimulation for Refractory Epilepsy

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Policy Statement

NHS England will commission Deep Brain Stimulation for refractory epilepsy in accordance with the criteria outlined in this document.

In creating this policy NHS England 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

Throughout the production of this document, due regard has been given to eliminate discrimination, harassment and victimisation, to advance equality of opportunity, and to foster good relations between people who share a relevant protected characteristic (as cited in under the Equality Act 2010) and those who do not share it.

Plain Language Summary

Selected patients with treatment resistant epilepsy can benefit from Deep Brain Stimulation (DBS). This is a procedure in which stimulating electrodes are placed into the deep structures of the brain. The electrodes are connected to an implanted pulse generator which is battery powered.

Successful DBS allows better control and minimisation of a patient's epileptic seizures. There are gains in movement and control. The intervention is used in carefully selected patients, in accordance with clinical eligibility criteria, who cannot be adequately controlled with drugs or whose drugs have severe side effects or for whom surgery is not possible.

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

1. Introduction

This policy considers the use of Deep Brain Stimulation (DBS) for patients with refractory epilepsy and states the criteria identifying which patients should be considered for this treatment.

2. Definitions

Deep Brain Stimulation (DBS) is a surgical treatment involving the implantation of a medical device called a brain pacemaker, which sends electrical impulses to specific parts of the brain. DBS in select brain regions has provided therapeutic benefits for otherwise treatment-resistant movement disorders. DBS directly changes brain activity in a controlled manner, the effects are reversible (unlike those of lesioning techniques) and is one of only a few neurosurgical methods that allows blinded clinical trials.

The Deep Brain Stimulation system consists of three components: the implanted pulse generator (IPG), the lead, and the extension. All three components are surgically implanted inside the body. Under local anesthesia, a hole about 14 mm in diameter is drilled in the skull and the electrode is inserted, with feedback from the patient for optimal placement. The installation of the IPG and lead occurs under general anesthesia. The IPG can be calibrated by a neurologist, nurse or trained technician to optimize symptom suppression and control side effects.

DBS leads are placed in the brain according to the type of symptoms to be addressed.

Deep Brain Stimulation for refractory epilepsy targets the Anterior Nucleus of the Thalamus (ANT). The ANT represents an attractive stimulation target due to its widespread thalamocortical projections.

Epilepsy is a neurological disorder characterised by seizures. Epileptic seizures are the result of excessive and abnormal cortical nerve cell activity in the brain. Seizures can vary from brief and nearly undetectable to long periods of vigorous shaking. People with epilepsy are at an increased risk of death.

Seizures are controllable with medication in about 70% of cases. Patients whose seizures do not respond to anti-epileptic drug therapy are considered to have refractory epilepsy.

3. Aim and objectives

The clinical questions being addressed are:

- a. Is there sufficiently robust evidence of clinical effectiveness and safety to support the use of DBS for patients with refractory epilepsy?

- b. If the evidence is sufficiently robust, what criteria should be used to identify suitable patients to be considered for DBS treatment for refractory epilepsy?

4. Epidemiology and needs assessment

Epilepsy is a highly prevalent disorder that is a major cause of morbidity in patients throughout the world. Nearly 1% of the population suffers from epilepsy, with an annual incidence of 50/100,000 people. In 60%–70% of epilepsy patients, treatment with antiepileptic medications results in seizure remission. The remaining patients, in whom symptoms are refractory to medications, currently have relatively limited alternative treatment options.

Perhaps the most effective option in patients with medically refractory epilepsy is resective epilepsy surgery, which involves the excision of the part of the brain causing the epilepsy. In patients with well-defined epileptic zones, this can offer a high likelihood of excellent long-term seizure control. In medically intractable patients in whom resection fails to control seizures, or for patients who are not appropriate candidates for surgery, there are a limited number of available palliative options, until recently.

Typically, refractory epileptic patients have frequent admission to hospitals and may require significant support from other government agencies. Epileptic patients tend to have a lower life expectancy and are at risk of sudden death in epilepsy (SUDEP). Consequently, any treatment that reduces seizures can improve mortality as well as minimise morbidity.

5. Evidence base

The SANTE trial was the first large, multicentre, double-blind, randomized trial that examined the effects of ANT DBS in patients with intractable epilepsy. A total of 110 patients underwent bilateral electrode implantations in the ANT. One month after implantation, the patients were then randomized to either a stimulation group or a no-stimulation group for a 3-month “blinded” phase. This was followed by a 9-month open-label phase in which all patients had their stimulators turned on and stimulation parameters were optimized to minimize adverse events. Long-term follow-up was achieved in 99 patients at 13 months and 81 patients at 25 months. The primary outcome assessed was monthly seizure rate. Secondary outcomes included the Liverpool Seizure Severity Scale, Quality of Life in Epilepsy Scale, and neuropsychological assessment.

At the end of the 3-month blinded phase, there was a 40.4% decrease in median seizure frequency in the stimulated group compared with a 14.5% decrease in the control no-stimulation group ($p = 0.0017$). That the control group also had a decrease in seizure frequency is consistent with previous studies showing an implantation effect. This effect alone, however, does not explain the significant difference between the stimulation and control group and suggests stimulation did

indeed have an effect. Patients with seizures originating from one or both temporal lobes had a significant difference in median seizure reduction in the stimulation group compared with the control group (44.2% and 21.8%, respectively; $p = 0.025$), while patients with seizures originating from the frontal, parietal, or occipital lobe did not.

During the long-term follow-up there was a 41% decrease in median seizure frequency at 13 months and 56% decrease at 25 months. Fourteen patients were seizure free for at least 6 months during the entire study. Nine patients had an increase in median seizure frequency at 25 months. The most common adverse event was paresthesias, reported in 18.2% of participants, which tended to occur during the 1st month of implantation. Depression and memory impairment occurred in significantly more people in the stimulation group during the blinded phase ($p = 0.0162$ and 0.0316 , respectively), although most were transient events and resolved during term follow-up.

The SANTE trial demonstrated the overall effectiveness of ANT stimulation as a palliative measure for reducing seizure frequency in patients in whom epilepsy is refractory to medical therapy. In addition, there were 14 patients who were seizure free for at least 6 months during the study period, indicating that some patients may benefit from ANT stimulation more than others.

There are serious but well known side effects, similar to other applications of DBS that have been widely adopted within the NHS. Therefore, this procedure should only be used with special arrangements for clinical governance, consent and audit.

No cost effectiveness studies for this specific use of Deep Brain Stimulation have been found. The DBS device is expensive and there is the additional cost of the procedure to implant the device.

Offset healthcare costs relating to DBS are attributable to a reduction in drug costs, in patient care, day care, community nursing, occupational therapy and GP home visits.

Offset social costs could be considerably higher. As an example, the median annual cost of a community care package is estimated at £9,776. This level of support consists of ten hours per week of social care (to support 4 activities of daily living) plus one GP home visit per month.

It is estimated that the number of devices implanted annually for refractory will be between 10 and 20. Despite the offset costs the overall situation is one of a cost pressure for NHS England.

6. Rationale behind the policy statement

It is evident that Deep Brain Stimulation in selected patients provides significant therapeutic benefits. The intervention is used for carefully selected patients in accordance with clinical eligibility criteria who are not suitable for resective surgery and cannot be adequately controlled with medications or whose medications have severe side effects.

NICE Interventional Procedure Guidance (IPG416) recommends the procedure is efficacious and safe if certain clinical governance, consent, audit and research requirements are met.

The NICE guidance states:

“Any treatment that is shown to reduce seizure frequency, SUDEP risk, need for medication and concomitant side effects to an extent which improves the lives of patients and their carers would be a welcome addition to the options for management.”

7. Criteria for commissioning

Refractory Epilepsy patients meeting all the following criteria will be routinely funded for Deep Brain Stimulation:

- The patient is between 18 and 65 years old
- Diagnosed as having epilepsy characterised by partial-onset seizures, with or without secondary generalisation
- Had at least 6 partial seizures per month but no more than 10 per day
- Seizures not adequately controlled with a trial of at least three anti-epileptics drugs
- All patients must have undergone prior assessment by the functional neurosurgery multi-disciplinary team (MDT).
- The selection of patients for Deep Brain Stimulation must have considered and discounted resective surgical treatment.

8. Patient pathway

The admission criteria indicate that Deep Brain Stimulation is the last line of therapy, only to be used after all other options have been exhausted or discounted.

9. Governance arrangements

Deep Brain Stimulation should only be performed in specialist centres willing to publish their results and use clinically relevant patient outcomes.

Outcomes should include measures of seizure frequency, functional ability, social inclusion and quality of life.

A National Toolkit for the Designation of Providers of DBS was published in September 2011 and set out the service standards for DBS providers in England.

10. Mechanism for funding

NHS England is responsible for funding the out patient and in patient treatment, which is part of the scope of adult neurosurgery.

11. Audit requirements

Clinical governance guidelines state that all British neurosurgical centres are required to audit their results

12. Documents which have informed this policy

1. NHS England Clinical Commissioning Policy (April 2013) : Deep Brain Stimulation in Movement Disorders
2. National Institute for Health and Care Excellence (NICE) Interventional Procedure Guidance (IPG416) : Deep Brain Stimulation for Refractory Epilepsy
3. Stimulation of the Anterior Nucleus of the Thalamus for Epilepsy (SANTE) trial : United States National Institute of Health

13. Links to other policies

1. NHS England Clinical Commissioning Policy (April 2013) : Deep Brain Stimulation in Movement Disorders

This policy follows the principles set out in the ethical framework that govern the commissioning of NHS healthcare and those policies dealing with the approach to experimental treatments and processes for the management of individual funding

requests (IFR).

14. Date of review

This policy will be reviewed in April 2018 unless information is received which indicates that the proposed review date should be brought forward or delayed.

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