Clinical Commissioning Policy: Deep Brain Stimulation for Refractory Epilepsy

Reference: NHS England D03/P/c
<table>
<thead>
<tr>
<th>Directorate</th>
<th>Medical</th>
<th>Commissioning Operations</th>
<th>Patients and Information</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Nursing</td>
<td>Trans. &amp; Corp. Ops.</td>
<td>Commissioning Strategy</td>
</tr>
<tr>
<td></td>
<td>Finance</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Publications Gateway Reference:</th>
<th>03737</th>
</tr>
</thead>
<tbody>
<tr>
<td>Document Purpose</td>
<td>Policy</td>
</tr>
<tr>
<td>Document Name</td>
<td>D03/P/c Deep Brain Stimulation for refractory epilepsy</td>
</tr>
<tr>
<td>Author</td>
<td>Specialised Commissioning Team, NHS England</td>
</tr>
<tr>
<td>Publication Date</td>
<td>July 2015</td>
</tr>
<tr>
<td>Target Audience</td>
<td>Local Team Assistant Directors of Specialised Commissioning; Regional Team IFR Leads; Finance Leads; Local Team Pharmacists; Chairs of Clinical Reference Groups; Members of Clinical Reference Groups and registered stakeholders; Acute Trust Chief Executives; Acute Trust Medical Directors; Acute Trust Chief Pharmacists</td>
</tr>
<tr>
<td>Additional Circulation List</td>
<td>Regional Medical Directors; Regional Directors of Specialised Commissioning; Regional Clinical Directors of Specialised Commissioning; Regional Directors of Nursing</td>
</tr>
<tr>
<td>Description</td>
<td>NHS England has adopted a policy to not routinely commission this specialised treatment as described in this document.</td>
</tr>
<tr>
<td>Cross Reference</td>
<td></td>
</tr>
<tr>
<td>Superseded Docs (if applicable)</td>
<td></td>
</tr>
<tr>
<td>Action Required</td>
<td></td>
</tr>
<tr>
<td>Timing / Deadlines (if applicable)</td>
<td></td>
</tr>
<tr>
<td>Contact Details for further information</td>
<td><a href="mailto:jeremyglyde@nhs.net">jeremyglyde@nhs.net</a> for policy issues</td>
</tr>
</tbody>
</table>

**Document Status**

This is a controlled document. Whilst this document may be printed, the electronic version posted on the intranet is the controlled copy. Any printed copies of this document are not controlled. As a controlled document, this document should not be saved onto local or network drives but should always be accessed from the intranet. **NB:** The National Health Service Commissioning Board was established on 1 October 2012 as an executive non-departmental public body. Since 1 April 2013, the National Health Service Commissioning Board has used the name NHS England for operational purposes.
## Contents

1. Executive Summary ................................................................. 4
   Policy Statement ................................................................. 4
   Equality Statement .............................................................. 4
   Plain Language Summary ....................................................... 4
2. Introduction ........................................................................... 5
3. Definitions ............................................................................. 5
4. Aims and Objectives ............................................................... 6
5. Epidemiology and Needs Assessment ......................................... 6
6. Evidence Base ....................................................................... 6
7. Rationale behind the Policy Statement ......................................... 7
8. Criteria for Commissioning ...................................................... 7
9. Patient Pathway ..................................................................... 7
10. Governance Arrangements .................................................... 7
11. Mechanism for Funding ......................................................... 7
12. Audit Requirements ............................................................... 7
13. Documents which have informed this Policy ............................ 7
14. Links to other Policies ............................................................ 8
15. Date of Review ..................................................................... 8
Appendix A ................................................................................ 8
1 Executive Summary

Policy Statement

NHS England will not routinely commission Deep Brain Stimulation for Refractory Epilepsy.

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.

Equality Statement

NHS England 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. NHS England is committed to fulfilling this duty as to equality of access and to avoiding unlawful discrimination on the grounds of age, gender, disability (including learning disability), gender reassignment, marriage and civil partnership, pregnancy and maternity, race, religion or belief, gender or sexual orientation. In carrying out its functions, NHS England 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 NHS England is responsible, including policy development, review and implementation.

Plain Language Summary

Deep brain stimulation 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.

DBS aims to provide better control and minimisation of a patient’s epileptic seizures, with gains in movement and control.
2 Introduction

This policy considers the use of Deep Brain Stimulation (DBS) for patients with refractory epilepsy.

3 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 Thalmus (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.

4 Aims and Objectives

This aims and objectives of this policy are to set out the NHS England commissioning position for Deep Brain Stimulation for Refractory Epilepsy.

5 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.

6 Evidence Base
NHS England considered the available clinical evidence as described by the Clinical Reference Group. NHS England concluded that there was not sufficient evidence to support the routine commissioning of this treatment for the indication. In the interests of transparency the clinical case that was put to NHS England by the CRG is set out in Appendix A.

7 Rationale behind the Policy Statement

Deep Brain Stimulation for Refractory Epilepsy has been considered by NHS England who concluded that there was not sufficient evidence to support the routine commissioning of this procedure.

8 Criteria for Commissioning

NHS England does not routinely commission Deep Brain Stimulation for Refractory Epilepsy.

9 Patient Pathway

Not applicable.

10 Governance Arrangements

Not applicable.

11 Mechanism for Funding

NHS England will not routinely fund Deep Brain Stimulation for patients with Refractory Epilepsy.

12 Audit Requirements

Not applicable

13 Documents which have informed this Policy

Not applicable
14 Links to other Policies

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).

15 Date of Review

This policy will be reviewed in April 2017 unless information is received which indicates that the proposed review date should be brought forward or delayed.

Appendix A

NHS England considered the available clinical evidence as described by the Clinical Reference Group. NHS England concluded that there was not sufficient evidence to support the routine commissioning of this treatment for the indication. In the interests of transparency the clinical case that was put to NHS England by the CRG is set out below for information.

“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.

The five year follow up data was published in March 2015 and concluded that the treatment achieved both a sustained and statistically significant reduction in seizure frequency from baseline that kept improving over time. At five years there was a 69% median seizure reduction.

68% of responders had a 50% or higher reduction in their seizures at five years, compared to 43% at one year.
Seizure severity lessened and patients reported statistically significant improvements to their quality of life versus baseline at five years.

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.”