



Clinical Commissioning Policy: Deep Brain Stimulation For Chronic Neuropathic Pain

Reference: NHS England D08/P/d

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Cross Reference	
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Document Status

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1 Executive Summary

Policy Statement

NHS England will not routinely commission Deep Brain Stimulation for Chronic Neuropathic Pain.

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

Neuropathic pain has been defined as pain resulting from a disease or lesion of the nervous system, for example due to stroke or brachial plexus avulsion. It is often chronic (i.e. long term) and the response to treatment with medication may be poor. Patients may require very large doses of expensive pain medicines specific for neuropathic pain, the efficacy of which for certain neuropathic pains is frequently poor, and side effects, particularly cognitive impairment, are almost universal.

Deep brain stimulation (DBS) involves the implantation of a device that delivers small electrical pulses to specific parts of the brain that are involved in pain perception, with the aim of masking the pain by producing other sensations such as buzzing or warmth in the painful area. The device is somewhat like a heart pacemaker except that the wires, rather than running into the heart, go into the brain through small holes in the skull.

2 Introduction

This policy considers the use of Deep Brain Stimulation (DBS) for Chronic Neuropathic Pain and states the commissioning position for the funding of this intervention by the NHS.

Neuropathic pain is pain arising from an injury to the nervous system. Overall, 7-8% of the European population suffer from neuropathic pain. Symptom severity and duration are often greater than for other types of pain, and pharmacological treatment is unsatisfactory for many patients, either because it is ineffective or because the dosages required to alleviate pain cause intolerable side effects. For patients with very severe chronic neuropathic pain that is refractory to all other treatments, neuromodulation may offer an alternative option that may be able to induce analgesia without the problems associated with pharmacotherapy. DBS is a surgical treatment involving the implantation of a medical device acting like a 'brain pacemaker', which sends electrical impulses to specific parts of the brain. By targeting specific areas (typically in the thalamus and periventricular grey matter) that play a part in pain perception, or related limbic areas that mediate the unpleasantness of pain.

NICE has provided relevant interventional procedure guidance (IPG382: Deep brain stimulation for refractory chronic pain syndromes (excluding headache)). NICE indicated that: "... this procedure may be used provided that normal arrangements are in place for clinical governance, consent and audit." This was issued in May 2011; however high quality published trial evidence is still lacking.

3 Definitions

Chronic pain: Pain that persists for more than 6 months.

Neuropathic pain: Pain caused by damage or disease that affects the somatosensory system

Central neuropathic pain: Pain caused by a lesion or disease of the central somatosensory nervous system.

Peripheral neuropathic pain: Pain caused by a lesion or disease of the peripheral somatosensory nervous system. See neuropathic pain note.

Deep Brain Stimulation (DBS): This is the treatment being considered in this document. DBS involves the surgical implantation of a medical device like a 'brain pacemaker', which sends small electrical impulses to specific parts of the brain. DBS has provided therapeutic benefits for otherwise treatment-resistant movement disorders including Parkinson's disease, dystonia, and tremor, for all of which it has now received routine funding approval. DBS leads are placed in the brain in precise locations that depend on the type of symptoms to be addressed. The stimulation directly changes brain activity in a controlled manner, the effects are reversible (unlike those of the surgical lesioning techniques that it has largely eclipsed). The deep brain stimulation system consists of three components: the depth leads (typically two in number) that are inserted into the brain, the implanted pulse generator (IPG) that contains a battery and circuitry to produce the stimulus current, and the extension leads that run subcutaneously to connect these together. All three components are surgically implanted inside the body. Experiences with DBS for movement disorders have established the safety and long term viability of all the technologies involved.

Depth leads: These are thin cables containing several wires (usually four) which run to electrodes on the end of the lead that goes into the brain. Most commonly two leads are implanted, but sometimes only one, and very occasionally more than two may be needed.

Implantable pulse generator (IPG): A device containing microelectronics and a battery to produce the stimulus current. The IPG can have either a non-rechargeable or rechargeable battery. The IPG can be programmed to deliver a precise electrical field to the nervous tissue; the patient using a hand held programmer can control it. The technology is similar to that of cardiac pacemakers and cochlear implants. The IPG is usually implanted in a similar place to a heart pacemaker, under the skin below the collar bone.

Extension leads: These are cables that connect the depth leads to the IPG. They are designed to be extremely flexible as they have to withstand being flexed back and forth as the neck moves.

Trial of Stimulation: Usually the implantation is done in two stages. At a first operation only the depth leads are inserted. They are connected to temporary extensions that pass out through the skin and run to a temporary external stimulus source. The system is then trialed, adjusting the external stimulus source as necessary to optimise the effect. At the end of the trial period, if the stimulation achieves pain reduction the system is completed with the implantation of the remaining components at a second operation. If ineffective, the depth leads are removed.

UWNPS = University of Washington Pain Score

BPI = Brief Pain Inventory

MPQ = McGill Pain Questionnaire

VAS Score = Visual Analogue Scale Score

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 Chronic Neuropathic Pain.

5 Epidemiology and Needs Assessment

The prevalence of chronic neuropathic pain symptoms in the general population is estimated at 6-8% (Bouhassira, Torrance 2013) and this pain is typically more severe than chronic pain of non-neuropathic origin (median pain score of 7.0/10 for chronic neuropathic pain compared to 5.0/10 for chronic pain of non-neuropathic origin).

The incidences of new cases of certain common types of neuropathic pain have been quantified in the UK (Hall 2006). Annual incidences per 100,000 population are 40 for postherpetic neuralgia, 27 for trigeminal neuralgia (TGN), 1 for phantom limb pain, and 15 for diabetic neuropathy. This suggests some 40,000 new cases per year in England, and does not include several less well quantified indications for which pain DBS has been used, including brachial plexus injury, spinal injury, facial pain as a complication of dental work, and importantly central post-stroke pain (CPSP) which is thought to affect at least 10% of stroke victims.

Most cases of chronic neuropathic pain can be treated medically. However, some 10% of patients are truly refractory to medication. It is probable that only a small minority of even these patients would be potential candidates for deep brain stimulation. For example, there are a number of surgical options in TGN (microvascular decompression, percutaneous rhizotomy, Gamma Knife), and DBS would very rarely be a treatment for TGN itself. DBS may however be considered useful in the approximately 2% of patients in whom attempted surgical management of TGN with certain procedures such as injection via the foramen ovale are complicated by anaesthesia dolorosa, a condition of severe pain (often worse than the original pain) that is almost unmanageable by anything other than DBS.

The likely number of candidates for DBS is very hard to predict. A pragmatic estimate, extrapolating from the figures of the specialized neurosurgical centre that has done most of the UK's neuropathic pain DBS (Oxford) suggests a caseload nationally of 80-100 cases/year.

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 Chronic Neuropathic Pain has been considered by NHS England who concluded that there was not sufficient evidence to support the routine commissioning of this procedure for this patient group.

8 Criteria for Commissioning

NHS England does not routinely commission Deep Brain Stimulation for Chronic Neuropathic Pain.

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 Chronic Neuropathic Pain.

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.

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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 reference base-line for this was the NICE IPG guidance published in March 2011. This was based on an evidence overview prepared in June 2010 focusing on clinical DBS studies of good quality containing information on safety and/or efficacy. These comprised 693 patients from 3 non-randomised comparative studies, 1 meta-analysis of case series and 5 case series. Publications included, dated from as early as the late 1970’s. Strongly positive commentaries were received from patients who had been treated by DBS. NICE in 2011, endorsed the use of DBS for refractory chronic pain syndromes in patients selected by a specialised pain MDT, when other treatments had failed to control their pain, provided informed consent, clinical governance, patient information and audit arrangements were in place. Keeping in mind the above NICE evidence review and Interventional Procedures Guidance recommendations, a further review was carried out using the NICE search strategy and the following studies identified:-

- a. *Boccard et al prospectively evaluated 197 chronic neuropathic pain patients for DBS suitability of which 85 patients progressed to DBS. Reasons for not proceeding to DBS included lack of NHS funding (56), surgery declined (29), medical/psychological contraindications (22), not truly refractory (3). Of the 85 - 31 had post-stroke pain, 9 had phantom limb/stump pain, 7 had brachial plexus (BP) avulsion, 13 had spinal damage, 15 had cephalgia and 10 had miscellaneous causes. Of the 85, 74 were implanted following a successful trial. Of these only 59 had long-term data. The success of DBS (EQ – 5D health state) varied by etiology, being most successful following Phantom Limb and Post-Stroke. Overall it was 66.1% (39 patients)*

with a mean follow-up of 28 months for this subgroup. At 3 months post-DBS, VAS had improved by 50% SF-36 by 38%, MPQ by 38% and EQ – 5D by 27%. These improvements were statistically significant and were sustained throughout the first year. Four years after DBS, VAS and health-state improvements showed some decline although SF 36, MPQ and EQ – 5D improvements remained stable. Complications seen were IPG changes, device removal and infections. This study is the largest open-label study of DBS for pain and uses current DBS technologies and current standards for neuroimaging and stereotactic surgery.

b. Pereira et al in a Portuguese centre treated 12 consecutive traumatic injury patients with DBS over 2009 – 2011. Patients were followed up for one year. The mean duration of symptoms before surgery was 20 ± 13.4 years. Eleven patients proceeded to full DBS implantation. Five patients were amputees and seven had Brachial Plexus Avulsions. Mean pre-op/baseline VAS scores were 8.2 ± 2.0 . At one month after surgery mean VAS scores improved by $60.1 \pm 27.3\%$, SF-36 improved by $30.1\% \pm 75.5\%$, UWNPS improved by $47.1\% \pm 33.3\%$ and BPI improved by $51.4\% \pm 33.3\%$. All improvements were statistically significant apart from SF-36 scores (except for physical functioning, physical role and bodily pain). Benefits demonstrated were sustained and remained significant at one year. Although both amputation and BPA subgroups showed significant improvements (as described above), amputation pain improved the most. No surgical complications or stimulation side-effects were noted.

b. Gray et al examined the post-operative effect of DBS on quality of life, emotional well-being and cognition, by a neuropsychological assessment carried out at least 6 months after patients had undergone DBS. Of 28 potential patients, 18 were available for the study. The sample's subjective post-op pain severity scores improved, significantly with mean reductions of 44.7% (BPI) and

50% (pain subscale of SF – 36). The latter however remained significantly different from a non-clinical sample. Statistically significant post-op functional improvements were also seen in FLP total disability scores of the order of 25.8%. Significant positive QOL improvements were shown in SF – 36 subscales for Physical role, Mental role and bodily pain. However although all SF – 36 sub scores showed an improvement, these were significantly impaired compared to non-clinical normative population data. Pre-operatively the sample's HAD – Anxiety and HAD- Depression scores measuring emotional well-being were both elevated compared with those of the non-clinical normative population. Following DBS surgery, the former scores were significantly reduced by 27.9% and 20.7% respectively. Whilst the reduction in the HAD anxiety score following DBS approached the population normative level, the post-operatively reduced HAD depression score remained elevated relative to the population level. Overall a positive effect with significant improvements in anxiety and mood were found. Post-surgery scores on all cognitive functioning measures were not significantly different from those of pre-surgery levels.

- c. Hunsche et al studied 4 patients suffering from intractable pharmaceutical therapy resistant thalamic pain affecting the whole hemi-body, lasting more than 2 years. Patients were assessed at 3, 6 and 12 months. Intra-operatively, all patients reported satisfying pain relief. In 2 patients a significant reduction of pain medication was achieved (50% reduction in 1 and 100% reduction in the other). In 1 patient successful pain relief vanished by the third month and only minor pain relief (10%) could be achieved. Overall 3 / 4 patients achieved long-lasting pain relief of more than 40%. This level of reduction in pain-intensity was demonstrable at 3, 6 and 12 months of follow-up post DBS. The study also demonstrated the feasibility of integrating tractography data into stereotactic planning of DBS in thalamic pain.

e. Inference from trials in related areas suggests that DBS for pain is likely to be cost effective. Although initial costs are high, these are offset by reduced requirement for health care resources over time. A cost-utility analysis comparing spinal cord stimulation (SCS) to conventional medical therapy for chronic pain syndromes including failed back surgery syndrome (FBSS), chronic regional pain syndrome (CRPS), peripheral arterial disease (PAD) and refractory angina pectoris (RAP) showed significant economic advantages of SCS in terms of cost per quality adjusted life year (cost per QALY) with probability of cost effectiveness varying from 75-95% depending on pathology (Rizvi et al 2013). Incremental cost effectiveness ratio (ICER) for SCS varied between CAN\$ 9,293 (FBSS) and CAN\$ 11, 216 (CRPS) (Rizvi et al 2013). Evaluation of cost-effectiveness of DBS for Parkinson's disease also found significant benefits over best medical therapy, even after start-up DBS costs were accounted for (Eggington et al 2014)".