NHS
Commissioning Board

Clinical Commissioning Policy: Deep Brain Stimulation (DBS) In Movement Disorders

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NHS Commissioning Board

Clinical Commissioning Policy: Deep Brain Stimulation (DBS) In Movement Disorders

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Contents

Policy Statement

The NHS Commissioning Board (NHS CB) will commission Deep Brain Stimulation (DBS) for patients with Parkinson's disease, tremor and dystonia in accordance with the eligibility criteria outlined in this document.

In creating this policy the NHS CB has reviewed these clinical conditions and the options for 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

Selected patients with treatment resistant movement disorders such as Parkinson's disease, tremor and dystonia 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 a decrease in medication or makes a medication regimen more tolerable. There are gains in movement and control. The intervention is used for carefully selected patients, in accordance with clinical eligibility criteria, who cannot be adequately controlled with drugs or whose drugs have severe side effects.

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

1. Introduction

DBS provides significant therapeutic benefits for otherwise treatment resistant movement and affective disorders such as Parkinson's disease, tremor and dystonia. This policy sets out criteria that need to be met for a patient with one of the three disorders to receive treatment at a centre in the UK, funded by the NHS CB.

2. Definitions

Parkinson's disease (PD) is a chronic disease of the brain characterised by gradually worsening tremor, muscle rigidity and difficulties with starting and stopping movements. In advanced stages of the disease there can be severe fluctuations between almost total immobility, with or without tremor, and hypermobility with abnormal involuntary movements (dyskinesia).

Dystonia is a movement disorder, a syndrome of sustained muscle contraction usually producing twisting and repetitive movements or abnormal postures. A number of different neurological diseases can cause the symptoms of dystonia. The disease can be disabling and is often accompanied by severe pain.

Tremor is also a symptom arising from a number of neurological diseases. It is an involuntary rhythmic repetitive movement, most frequently affecting the upper limbs. It can occur at rest or be triggered by posture or intentional movement. Severe tremor can be disabling because it affects fine-movement co-ordination.

Deep Brain Stimulation (DBS) is a procedure in which stimulating electrodes are placed stereotactically into the deep structures of the brain. The electrodes are connected to an implanted pulse generator which is battery powered. Typically the eeleelectrodes are secured to the skull and a cable tunnelled to the pulse generator situated in the front of the chest, although other positions are used. electrodes are secured to the skull and a cable tunnelled to the pulse generator situated in the front of the chest, although other positions are used. electrodes are secured to the skull and a cable tunnelled to the pulse generator situated in the front of the chest, although other positions are used.
electrodes are secured to the skull and a cable tunnelled to the pulse generator situated in the front of the chest, although other positions are used. Battery replacements are required at intervals (measured in years). Rechargeable systems have been developed with a usual lifespan of ten years.

3. Aim and objectives

DBS in selected patients has provided significant therapeutic benefits. Successful DBS allows a decrease in medication or makes a medication regimen more tolerable. There are gains in movement and control. Consequently, the intervention is used for patients who cannot be adequately controlled with medications or whose medications have severe side effects.

4. Criteria for commissioning

Parkinson's Disease

DBS is routinely commissioned for patients with this condition in accordance with the following criteria:

An established diagnosis of Parkinson's Disease as assessed by the UK Parkinson's Disease Society Brain Bank Criteria

The patient is fit to undergo DBS surgery under general anaesthesia (which is assessed by an anaesthetic opinion) with no contra-indications for surgery (e.g. sepsis/coagulopathy)

Be considered to have a life expectancy of 5 or more years as assessed by a detailed medical history and post liaison with other professionals.

Have symptoms of motor complications severe enough to significantly compromise function and quality of life as supported by PDQ39 and Unified Parkinson's Disease Rating Scale (UPDRS) Part II scores. These symptoms will include those who have shown to be responsive to DBS: on/off fluctuations; L-dopa induced dyskinesias or medication resistant functionally impairing tremor.

If the indication is on/off fluctuations and or L-dopa induced dyskinesias:

- Assessment will show the patient is spending more than 30% of a 24 hour period in either a disabling off state or with disabling dyskinesia. This will be supported by detailed clinical history, patient diaries UPDRS Part IV scores, and will be despite optimisation of best medical therapy as determined by a consultant neurologist in a functional neurosurgery for movement disorders team. Strategies such as adding a catechol-O-methyl transferase (COMT) inhibiter, adding a monoamine oxidase inhibitor (MAOI), switching to long acting agonists or adding amantadine for dyskinesia should have been tried and failed or be considered unsuitable.
- A L-dopa response of greater than or equal to a 40% improvement in Part III Unified Parkinson's Disease Rating Scale (UPDRS) motor scale sub-scores following a practically defined period off medication has been shown.

If the indication is medication resistant functionally impairing tremor:

- This will have been shown by detailed assessment to be sufficiently severe to significantly impair activities of daily living to a degree that impairs quality of life as supported by PDQ39, UPDRS II scores and a clinical tremor rating scale (Fahn Tolosa Marin (FTM) tremor rating scale)
- All options for best medical therapy will have been considered, tried or exhausted by a movement disorder consultant neurologist working with a

functional neurosurgery team

Patient is free from clinically significant cognitive impairment measured by DRS 2 (score of 6 or below). If clinical concern has led to more detailed neuropsychometry this has not shown evidence of clinical dementia.

Dystonia

DBS is routinely commissioned for patients with this condition in accordance with the following criteria:

Generalised Dystonia

An established clinical diagnosis of generalised dystonia as determined by a consultant neurologist in a functional neurosurgery for movement disorders team

The patient is fit to undertake DBS under general anaesthesia (which is assessed by an anaesthetic opinion) with no contra-indications for surgery (e.g. sepsis/coagulopathy)

Exhibits focal or generalised dystonia of sufficient severity to compromise quality of like as supported by the Burke Fahn Marsden Dystonia Rating Scale (BFMDRS)

The dystonia is the primary cause of the disability

There are no significant postural defects or significant fixed joint deformities

Has had a two month trial of appropriate dose levodopa to exclude dopa responsive dystonia or not felt to be clinically indicated

All other medical and surgical interventions have been considered and exhausted. In the case of medical interventions dystonia will have been shown to be refractory to the use of best medical therapy post assessment by a movement disorder consultant neurologist working with a functional neurosurgery team

The diagnosis is not one of psychogenic dystonia

Status Dystonicus

Patient is seen by a consultant neurologist (paediatric) and neurosurgeon to arrive at final decision

Patient has severe and frequent episodes of generalised dystonia which require urgent hospital admission with or without systemic complications (e.g. respiratory or renal compromise, rhabdomyoysis)

Presence of an established diagnosis for the underlying disease resulting in status

Any underlying trigger for the status dystonicus has been identified and treated

Patient's condition is refractory to medical management which includes sedation, muscle relaxation and supportive treatment

Patient is fit to undergo deep brain stimulation surgery under general anaesthesia without contra-indication to DBS surgery (significant brain atropy or pathology in anatomical area targeted for dystonia)

Laryngeal Dystonia

Laryngeal dystonia with significant risk of aspiration pneumonia is a particular indication as DBS may be the only effective treatment and the condition may be life threatening

Cervical Dystonia

An established diagnosis of cervical dystonia as determined by a consultant neurologist in a functional neurosurgery for movement disorders team

The patient is fit to undergo DBS surgery under general anaesthesia (which is assessed by an anaesthetic opinion) with no contra-indications for surgery (e.g. sepsis/coagulopathy)

Exhibits cervical dystonia of sufficient severity to compromise quality of life as supported by the Toronto Western Spasmodic Torticollis Rating Scale (TWSTRS) score

The dystonia is the primary cause of the disability

There are no significant postural defects or significant fixed joint deformities

Selective peripheral denervation has been considered and excluded or undertaken and failed to produce an adequate response.

Patient did not have an adequate response to botulinum toxin treatment or failed to tolerate botulinum toxin treatment or requires such large or frequent treatments with botulinum toxin as to make such treatment impractical or unsuitable for botulinum toxin treatment

Essential or Dystonic Tremor

DBS is routinely commissioned for patients with this condition in accordance with the following criteria:

An established diagnosis of essential tremor or dystonic tremor as determined by a consultant neurologist in a functional neurosurgery for movement disorders team

Tremor sufficient to significantly impair activities of daily living to an extent that impairs quality of life supported by a clinical tremor rating score (FTM tremor

rating scale)

The patient is fit to undergo DBS surgery under general anaesthesia (which is assessed by an anaesthetic opinion) with no contra-indications for surgery (e.g. sepsis/coagulopathy)

All other medical and surgical interventions have been considered and exhausted or are not felt to be applicable post assessment by a movement disorder consultant neurologist in a functional neurosurgery for movement disorders team. For essential tremor; Beta blockers over a four month period have been tried and failed or not tolerated or not applicable, Primidone over a four month period has been tried and failed or not tolerated or not applicable, Gabapentin over a four month period has been tried and failed or not tolerated or not applicable, Topirimate over a four month period has been tried and failed or not tolerated or not applicable. For dystonic tremor anticholinergics over a four month period have been tried and failed or not tolerated or not applicable

Treatment of tremor is likely to produce a functionally useful improvement in disability

Mid Brain Tremor

An established diagnosis of mid brain tremor as determined by a consultant neurologist in a functional neurosurgery for movement disorders team

Mid brain tremor should have an established aetiology and be severe enough to significantly compromise quality of life and performance of activities of daily living as supported by a clinical tremor rating scale score (FTM tremor rating scale)

The patient is fit to undergo DBS surgery under general anaesthesia (which is assessed by an anaesthetic opinion) with no contra-indications for surgery (e.g. sepsis/coagulopathy)

All other medical and surgical interventions have been considered and exhausted or are not felt to be applicable post assessment by a movement disorder consultant neurologist in a functional neurosurgery for movement disorders team

A trial of Gabapentin over four months has been tried and failed or not tolerated or not applicable

A MRI has been performed which does not demonstrate pathological involvement/destruction of the target site for DBS

The underlying diagnosis is multiple sclerosis and the predominant functional impairment is felt to be due to tremor rather than ataxia plus there is not sufficient spasticity, weakness, numbness or perioperative loss to prevent a return of function if tremor is removed OR the underlying diagnosis is infarction and there is not sufficient spasticity, weakness, numbness or perioperative loss to prevent a return of function if tremor is removed

5. Patient pathway

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

6. Governance arrangements

DBS should only be performed in experienced specialist centres willing to publish their results and use established clinically relevant patient outcomes. Standards were co-ordinated by the National Specialist Commissioning Advisory Group in England and Wales and designated DBS centres to participate in the PD-SURG trial.

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.

7. Epidemiology and needs assessment

A very small sub group of the disease would meet the clinical eligibility criteria for Deep Brain Stimulation. For example, Parkinson's disease is common, affecting 0.5% people aged 65 to 74 years and 1% to 2% of people aged 75 years and over. Of this group the numbers likely to be eligible for DBS ranges from 1% to 10%. East Midlands Specialised Commissioning Group identified a prevalence for Parkinson's disease of 6,546 and an incidence of 1,093 within a population of approximately 4.5 million. The application of eligibility criteria produced an estimate of 27 DBS patients per year with Parkinson's disease. A crude pro rata to England's population would indicate about 300 patients per year plus patients for dystonia and tremor.

8. Evidence base

DBS for Parkinson's disease: evidence summary

DBS to the subthalmic nucleus (DBS-STN) improves self reported quality of life at 6 months, one year, 18 months, and 24 months over best medical treatment (BMT) as measured by the PDQ39, by approximately 30%.[1, 2, 5, 8]

DBS-STN reduces motor complications of PD at 6 months, one year, 18 months and 24 months by approximately 70% when compared to BMT. The clinical outcome directly capturing this is reduction in daily off time and on time with dyskinesia, as shown by changes in patient diaries and part IV UPDRS scores. [1, 2, 5, 8]

Blinded studies show a similar effect size in terms of reducing part III motor UPDRS off motor scores to that seen in non-blinded control studies.[2]

A marked improvement in walking time (stand-walk-sit test) seen with DBS (30%) in PD versus medical therapy (0%) has been shown.[2]

A very severe functionally impairing drug resistant tremor which continues with action and is sufficient to severely affect activities of daily living is rare in PD. Improvement in such a tremor in PD with DBS to the zona incerta (ZI) has been shown to be greater than 80%.[46]

In the PD Surg trial over 1/3 of patients were on apomorphine in the medical arm by one year to control motor fluctuations.[1]

The average total reduction in PD medication (L-dopa equivalents) is greater than 1/3 post DBS at one year and continues out to 5 years. [1, 50]

The Weaver trial contained a significant proportion of PD patients over the age of 70 and their outcomes were similar to the below 70 age group. In reality, however, DBS for PD is hardly ever offered to PD patients over the age of 75. This is due largely to a combination of cognitive decline, falls risk, comorbidities and surgical risk.[2]

The Rodriguez-Oroz, Krack and Schupbach studies show a non-declining (same as year 1 improvement) sustained benefit in off medication UPDRS part III scores of 50% with DBS at 4 and 5 years. Benefits in motor fluctuations and tremor continue up to 5 year.[50, 52, 62]

The reported range of adverse events is very variable across the literature. Although severe adverse events were more common in the DBS group adverse events per-se were more common in the medication group.[2]

Concerns have previously been raised about STN DBS producing cognitive changes, particularly executive function / verbal fluency. The Weaver trial was particularly strong in terms of the psychometric outcome data collected and did not demonstrate a clinically impairing effect in this regard.[2]

There is no evidence that DBS is neuroprotective in PD and the progression of pathology is not slowed.

DBS for Parkinson's disease: gaps in knowledge

It is difficult to relate changes to the UPDRS scores and PDQ39 scores to the impact for patients. The Weaver and Deuschl papers[2, 5] detail this further and include statements that in clinical terms improving good quality on time by 70% means moving patients from spending many hours in the day unable to stand, walk and perform ADLs to being easily able to stand, mobilize and function well in ADLs.

Duodopa now is now an option in BMT although cost effectiveness studies have not included this new agent which is an alternative when apomorphine is not tolerated. Poor tolerance of apomorphine due to confusion, psychosis and hypersomnolence is common. Note that in the US apomorphine is not available therefore caution must be taken when looking at the BMT arm in US studies. [2,8]

Long-term studies are limited to up to 5 years post DBS. PDsurg[1] has only reported outcomes at 12 months. After one year the vast majority of patients in the BMT arm elected for DBS and therefore comparison to BMT after this point will and can only be against a theoretical / projected control group. The medical arm of the study was limited to 12 months due to trial design and expectations around patient choice.

The optimum time to intervene in the course of the disease is uncertain. Treating patients earlier in their disease may offer the potential for benefit continuing for significantly longer than 5 years[50]. There is strong evidence that STN DBS should not be performed in patients with clinically significant cognitive decline (dementia), marked postural instability, 'on' freezing or 'on' falls.

DBS for Parkinson's disease: evidence of cost-effectiveness

In the absence of conclusive evidence on the cost-effectiveness of DBS, NICE CG 35 undertook economic modelling over a 5 year period and suggested that bilateral STN DBS costs £19,500 per QALY in comparison to standard PD care in the UK (£2998).

The model assumed that correlations between changes in UPDRS III (motor function) and QoL found in one study at 12 months could be applied to changed in UPDRS III scores for years 2 to 5 and that these changes would be maintained.

One way sensitivity analysis showed that total STN DBS procedure costs (which included the cost of initial surgery, follow-up appointments and inpatient follow up for stimulator adjustment/battery replacement) had the most impact on the Incremental Cost Effectiveness Ratio (ICER) with a range of ICER estimates from £87073 to £30,854 per QALY.

The model underestimates the cost of initial surgery (estimated at £12,740 to £14,450 compared with 2010/11 costs of £26,070).

NICE commented that conclusive evidence on the cost effectiveness of this procedure awaited the results of the PDSurg trial. No other cost-effectiveness studies relevant to the UK healthcare system have been found.

Offset healthcare costs relating to DBS are attributable to a reduction in drug costs (likely to be modest), inpatient care, day care, community nursing, and 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 to be £9776 per annum (£188 per week). This level of support consists of 10 hrs per week of social care

(to support 4 activities of daily living) plus on GP home visit per month. A move from living at home to residential care will incur a larger individual and social cost.

DBS for Generalised dystonia: evidence summary

The target of choice in the brain is the Globus Pallidus (GPi) through bilateral stimulation, except when the predominant problem is dystonic tremor when either the ZI or the thalamus is targeted.

Pallidal DBS is a “good option” for primary generalized dystonia if symptoms are sufficient to impair activities of daily living to an extent that reduces quality of life. DBS, however, should only be employed for generalized dystonia after Botulinum A and B as well as drug therapy have been shown to have failed or considered to be unsuitable.[90]

DBS GPi reduces the BFMDRS movement score, the BFMDRS disability score, and GCI dystonia at 3 months when compared to sham stimulation. One class I randomized sham-controlled study with a crossover design at 3 months found that in patients with primary generalized and segmental dystonia the change from baseline in the mean dystonia motor score was significantly greater by approximately 40% in the neurostimulation group (15.8 ± 14.1 points) than in the sham stimulation group (1.4 ± 3.8 points).[64]

Three months is the minimal time at which efficacy in dystonia can be measured; the nature of the disease is such that maximal improvement is seen at 1-2 years which has been reported by other studies with longer cohort periods. Longer term efficacy has been reported as sustained for more than 5 years of follow-up.[67, 75, 81, 84]

DBS GPi improves the HRQoL at 3 months when compared to sham stimulation.[63]

DBS GPi was shown to reduce the BFMDRS at 6-36 months in uncontrolled studies. These studies[96, 91, 112] provide class II-III evidence and support the efficacy and safety of DBS of the GPi in selected patients with primary generalized or segmental dystonia. These have blinded assessment; either blinded video evaluation or double-blind assessment randomized to off or on DBS. Clinical outcomes (BFMDRS) in primary generalized dystonia show an average 50% improvement in dystonia severity with a 45% mean improvement in disability. Sustained benefit was seen in one of the studies for up to 3 years.[96]

Class IV studies have shown significant improvement in outcomes after DBS compared with baseline for patients with primary segmental and generalised dystonia.[63, 65, 86]

DBS GPi was shown to reduce drug doses by 32% at 6 months in an uncontrolled study.[64]

In children with primary dystonia DBS led to improvement in motor scores which was maintained at several years follow up.[67] Marked reduction in pain post improvement in dystonic movements is widely reported following DBS.

Adverse events include: hardware related complications such as lead breakages or dysfunction; dysarthria; infection; wound breakdown. Most reported adverse events are mild and can be managed through changes in stimulator settings.[96]

Adults with primary generalized dystonia without a DYT1 genetic mutation show a similar level of dystonia improvement with DBS to patients +ve for a DYT1 mutation, in the range of 40-90%.[98, 101, 104]

DYT-1 +ve status is a positive predictive factor of functional benefit for children with primary dystonia.[74]

There are no prospective studies on the effect of DBS in secondary dystonia

The response to DBS in secondary dystonia overall showed an improvement in movement and disability but was very variable. In one case series 4/8 patients demonstrated only slight to undetectable benefit.[77]

Patients with dystonia and choreoathetosis because of cerebral palsy may achieve limited benefit with motor scores improving between 10 – 40%, but nevertheless yielding acceptable patient satisfaction in some patients.[72]

Tardive dystonia, however, as opposed to other secondary dystonias appears to be a good indication for Gpi DBS with benefits similar to those seen in primary dystonia.[108]

DBS was effective in 3 patients with status dystonicus, 2 within 1 week, 1 over 3 months.[95]

DBS for Cervical dystonia: evidence summary

DBS should only be considered where Botox B and Botox A have been tried and failed or not possible for the type of dystonia.[90]

In a class II trial, the TWSTRS dystonia severity score improved from a mean of 14.7 ± 4.2 before surgery to 8.4 ± 4.4 (43% reduction) at 12 months postoperatively.[112] Disability and pain scores improved by 64% and 65% respectively.

DBS was shown to improve the TWSTRS scores from 3 months in an uncontrolled study of 6 patients with cervical dystonia.[110]

DBS showed improvement in TWSTRS severity and disability scores at a similar level to selective peripheral denervation. The pain scores showed a trend towards a reduction in the DBS group in a study of 24 patients with cervical dystonia.[109]

TWSTRS scores were shown to: improve gradually in the first year after DBS in an uncontrolled study of 4 patients with cervical dystonia[115] to improve significantly in 6/10 patients with cervical dystonia[113]; maintain improvement at 20 months.[117]

DBS for dystonia: gaps in knowledge

The level of the quality of evidence of DBS in dystonia is low, with only one published RCT to date.

The course and severity of generalised dystonia can fluctuate posing a particular problem in interpreting studies that lack controls.

The use of non-RCT studies in presenting a body of evidence is likely to overestimate the benefits and underestimate the adverse events.

There were no cost effectiveness assessments identified for this review

The numbers of patients in the care series of cervical dystonia are small, however this reflects the very small numbers of patients who are refractory to botulinum toxin A or B and therefore suitable for surgery. It is not expected that the numbers will ever reach those that are seen in the 40 patient generalised dystonia sham controlled study.

DBS for tremor: evidence summary

A systematic review of DBS for essential tremor (ET) reports that in all 17 studies reviewed there was a significant improvement in tremor outcomes after DBS compared with baseline scores (Fahn Tolosa Marin (FTM) tremor rating scale) in every study.[120]

There are no controlled trials of DBS for tremor with a comparison to best medical treatment

Where reported, bilateral stimulation seemed more effective than unilateral surgery.[133, 153]

Tremor scores have been shown to be improved in uncontrolled studies comparing before and after DBS. They consistently report an average 80% improvement in the FTM tremor rating scale. With a range of 59-100% and an average effect size estimate of 1.3 (range 0.77–1.95), representing a large effect size difference.[132, 133, 134, 138, 141. 144, 145]

Three studies have reported preoperative baseline ADL scores, and each reported an improvement from preoperative ADL scores to last follow-up.[134, 141, 147]

Adverse events include infection, poor wound healing, lead breakage, paraesthesia, pain, dysarthria, balance difficulties. More severe events are relatively rare, although studies poorly report the overall long-term outcomes related to these events.[120]

Bilateral zona incerta stimulation may be less likely to cause dysarthria than bilateral thalamic DBS. ZI stimulation is reported to improve tremor by over 80%.[128]

DBS can improve anxiety, quality of life in uncontrolled case series.[149]

The benefit of DBS reduces over the years following treatment.[141]

Similar to DBS, thalamotomy is effective in 73%-93% of patients but is accompanied by permanent complications in 9%-23% and dysarthria can be as high as 75% in bilateral thalamotomy.[156]

Lesion surgery has therefore not been considered ethical post the establishment of DBS, where side effects can typically be reversed by changes in stimulator settings.

DBS for tremor: gaps in knowledge

The duration of benefit beyond 5 years is not reported, however, ET is not typically considered to be a neurodegenerative condition and clinicians report stable long-term benefit.

9. Rationale behind the policy statement

It is evident DBS in selected patients provides significant therapeutic benefits. Successful DBS allows a decrease in medication or makes a medication regimen more tolerable. There are gains in movement and control. The intervention is used for carefully selected patients in accordance with clinical eligibility criteria who cannot be adequately controlled with medications or whose medications have severe side effects.

10. Mechanism for funding

As indicated by the scopes of the Adult Neurosurgery and Neurosciences Clinical Reference Groups DBS surgery would be funded by the NHS CB via payment for the appropriate healthcare resource group (HRG) and additionally for the stimulator, which is an excluded device under Payment by Results. Subsequent replacement batteries are similarly funded by the NHS CB. All neurology and neurosurgery out patients before and after surgery would be funded by the NHS CB. The mechanism operated by the NHS CB for funding requests outside of the clinical criteria in section 4 will be as per policy.

11. Audit requirements

Service providers will be expected to collect and provide audit data on request

12. Documents which have informed this policy

South West Specialised Commissioning Group Deep Brain Stimulation Policy
East of England Specialised Commissioning Group Deep Brain Stimulation for Parkinson's Disease, Tremor and Dystonia
East Midlands Specialised Commissioning Group Deep Brain Stimulation Policy
National Toolkit for the Designation of Providers of Deep Brain Stimulation
NICE IPG 019 for Parkinson's Disease
NICE IPG 188 for tremor and dystonia
NICE CG 35 for Parkinson's disease
Parkinson's Disease Society Brain Bank diagnostic criteria
http://www.brainexplorer.org/tables/Table%201.pdf Accessed 9/8/12

13. Links to other policies

Policy statement on the use of DBS for indications excluding movement disorders Individual Funding request Policy.

14. Date of review

During 2013/14

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Key Words: Deep brain stimulation/DBS/movement disorders/Parkinson's disease/QoL

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Bibliography Deep Brain Stimulation for Primary and Secondary Dystonia

14/09/2010 Search Strategy: MEDLINE/PUBMED/Cochrane Database

Key Words: Deep brain stimulation/DBS/primary dystonia/secondary dystonia/movement disorders/pallidum/Gpi/ n>10

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Product Name	Deep Brain Stimulation (DBS) in Movement Disorders
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