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Welsh Health Specialised  
Services Committee (WHSSC)

# **Specialised Services Commissioning Policy: CP28**

## **Deep Brain Stimulation (for people aged 16 and over)**

*July 2023*  
*Version 6.0*



## Document information

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<b>Description</b>	NHS Wales routinely commission this specialised service in accordance with the criteria described in this policy
<b>Document No</b>	CP28
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## **Policy Statement**

Welsh Health Specialised Services Committee (WHSSC) will commission Deep Brain Stimulation for people aged 16 years and older with movement disorders including Parkinson's disease, Tremor and Dystonia in accordance with the criteria outlined in this document.

In creating this policy WHSSC has reviewed this clinical condition and the options for its treatment. It has considered the place of this intervention 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.

## **Disclaimer**

WHSSC assumes that healthcare professionals will use their clinical judgment, knowledge and expertise when deciding whether it is appropriate to apply this policy.

This policy may not be clinically appropriate for use in all situations and does not override the responsibility of healthcare professionals to make decisions appropriate to the circumstances of the individual patient, in consultation with the patient and/or their carer or guardian.

WHSSC disclaims any responsibility for damages arising out of the use or non-use of this policy.

## **1. Introduction**

This policy has been developed for the planning and delivery of Deep Brain Stimulation (DBS) for people aged 16 and over with movement disorders including Parkinson's disease, Tremor and Dystonia and are resident in Wales. This service is only commissioned by the Welsh Specialised Services Committee (WHSSC) and applies to residents of all seven Health Boards in Wales.

### **1.1 Plain Language Summary**

Deep Brain Stimulation (DBS) is a neurological intervention for the management of severe movement disorders in people whose symptoms are resistant to medical therapy. These conditions are usually treated with drugs, but surgery may be considered for people who have responded poorly to drugs and/or who have severe side effects from medication.

DBS is a procedure in which stimulating electrodes are placed into a target area of the brain. The electrodes are connected to a battery powered implantable pulse generator, which is inserted under the skin of the chest wall<sup>1</sup>.

### **1.2 Aims and Objectives**

This policy aims to define the commissioning position of WHSSC on the use of Deep Brain Stimulation (DBS) for the treatment of movement disorders which includes Parkinson's disease, Tremor and Dystonia.

The objectives of this policy are to:

- ensure commissioning for the use of DBS is evidence based
- ensure equitable access to DBS
- define criteria for people with severe movement disorders (Parkinson's, Tremor and Dystonia) to access treatment
- improve outcomes for people with severe movement disorders, whose systems are resistant to medical therapy.

### **1.3 Epidemiology**

#### **Parkinson's Disease**

The prevalence of Parkinson's disease increases with age and it is higher for men than for women. For men aged 50-89, prevalence is 1.5 times higher than for women in the same age-group. The results from the Clinical Practice Research Datalink Summary report<sup>2</sup> estimated that the prevalence of Parkinson's disease for people over the age of 20 in 2018, for the

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<sup>1</sup> <https://www.england.nhs.uk/wp-content/uploads/2013/04/d03-p-b.pdf>

<sup>2</sup> <https://www.parkinsons.org.uk/sites/default/files/2018-01/CS2960%20Incidence%20and%20prevalence%20report%20branding%20summary%20report.pdf>

population of Wales would be in the region of 7,692. With an ageing population growth, the level of prevalence is likely to increase by 18% between 2018 and 2025.

It is estimated that between 1 and 10% of every person with Parkinson's disease would benefit from this procedure.

## **Tremors**

The prevalence of essential tremors increases with age and is considered one of the most common neurological movement disorders. It is 20 times more prevalent than Parkinson's Disease. It is a slowly progressive chronic condition. It is characterised by involuntary, rhythmic tremor of a body part, most typically the hands and arms<sup>3</sup>. It affects around four in 100 adults over 40 years of age. Some people only have a mild tremor at first, which usually gets more severe over time.

## **Dystonia**

Dystonia currently affects approximately 70,000 people in the UK<sup>4</sup>. Adult onset of Dystonia is prevalent between the ages of 30- 70 years old and is generally focal in one area. Dystonia is a movement disorder which causes involuntary spasms and contractions<sup>5</sup>. 90% of the dystonia cases are either cervical (which affects the neck muscles) or blepharospasm (which affects the eyelids) dystonia. These are both focal dystonia's, which occur later in life.

### **1.4 Current Treatment**

Current treatment options for the management of severe movement disorders in patients is usually treated with drugs but surgery may be considered in people who have responded poorly to drugs, who have severe side effects from medication, or who have severe fluctuations in response to drugs (on-off syndrome). Deep Brain Stimulation (DBS) treatment can lead to a reduction in the use of medication, can make a medication regimen more tolerable and can improve movement and control.

DBS involves the implantation of a wire into a target area in the brain. The wire is connected to a programmable pulse generator, which is inserted under the skin of the chest wall. The pulse generator can then be switched on and off by the patient, and the pulse width, stimulation amplitude and frequency can be adjusted by medical staff to optimise the effect of the stimulation. The battery will last up to approximately 5 years, at which time the entire pulse generator has to be replaced. Rechargeable systems have now been developed, with a battery life of 10 years.

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<sup>3</sup> [How to spot a tremor](#)

<sup>4</sup> [The Dystonia Society | What is dystonia?](#)

<sup>5</sup> [NHS Direct Wales - Encyclopaedia : Dystonia](#)

Currently there are two gatekeepers for the service. For south Wales, a Consultant Neurologist based in Aneurin Bevan UHB with patients referred to the North Bristol NHS Trust for pre, post-operative and follow up outpatient treatment and for patients from North Wales, a Neurologist based in the Walton Centre with patients referred to a Neurosurgeon in the Walton Centre for treatment.

### **1.5 Proposed Treatment**

WHSSC has undertaken a review of the service provision across South and Mid Wales and identified that there are service accessibility issues. WHSSC plans to review the long term service and investment requirements and consider these changes in conjunction with the WHSSC Integrated Commissioning Plan.

### **1.6 What we have decided**

WHSSC has carefully reviewed the evidence of Deep Brain Stimulation for the management of severe movement disorders in patients whose symptoms are resistant to medical therapy. We have concluded that there is enough evidence to fund Deep Brain Stimulation within the criteria set out in this policy.

### **1.7 Relationship with other documents**

This document should be read in conjunction with the following documents:

- **NHS Wales**
  - All Wales Policy: [Making Decisions in Individual Patient Funding requests](#) (IPFR).
- **NICE guidance**
  - [Deep Brain Stimulation for Parkinsons Disease](#). NICE Interventional procedures guidance [IPG19], November 2003.
  - [Deep brain stimulation for tremor and dystonia \(excluding Parkinson's disease\)](#) NICE Interventional procedures guidance [IPG188], August 2006.
- **Relevant NHS England policies**
  - Clinical Commissioning Policy: [Deep Brain Stimulation \(DBS\) in Movement Disorders \(Parkinson's Disease, Tremor and Dystonia\)](#), April 2013, Reference: NHSCB/D03/P/b.



## 2. Criteria for Commissioning

The Welsh Health Specialised Services Committee approve funding of Deep Brain Stimulation (DBS) for the treatment of movement disorders, which includes Parkinson's disease, Tremor and Dystonia for people aged 16 and over.

### 2.1 Inclusion Criteria

WHSSC will fund the treatment of DBS for people aged 16 and over with a diagnosis of:

- Parkinson's Disease
- Generalised Dystonia
- Focal and Segmental Dystonia
- Cervical Dystonia
- Status Dystonicus
- Essential or Dystonic Tremor
- Mid Brain Tremor

Replacement generators:

- WHSSC will fund the replacement of pulse generators on the grounds that the device is no longer functioning and that withdrawal of treatment would be to the detriment of the patient.

DBS is only routinely commissioned for people aged 16 years and over that meet all of the general criteria in section 2.1.1, **and** the revised criteria for either Parkinson's disease (see section 2.1.2) **or** Dystonia (see section 2.1.3 -2.1.6) **or** Tremor (see section 2.1.7 – 2.1.10).

#### 2.1.1 General Criteria

People aged 16 years and older, **and**

- are in good general health and are considered to have a life expectancy of 5 or more years as assessed by a detailed medical history and post liaison with other professionals
- symptoms are severe enough to significantly compromise quality of life and the activities of daily living, **and**
- have no evidence of dementia or current serious non drug related psychopathology, **and**
- are fit to undergo DBS surgery under general anaesthesia with no contra-indications for surgery (e.g. sepsis/coagulopathy).

### 2.1.2 Parkinson's Disease

People aged 16 years and older that meet all of the general criteria in section 2.1.1, **and**:

- have an established diagnosis of Parkinson's Disease as assessed by the UK Parkinson's Disease Society Brain Bank Criteria, **and**
- have symptoms of motor complications severe enough to significantly compromise function and quality of life - on/off fluctuations; L-dopa induced dyskinesias or medication resistant functionally impairing tremor, **and**
- all other medical and surgical interventions have been considered and exhausted or are not felt to be applicable, **and**
- are free from clinically significant cognitive impairment.

### 2.1.3 Generalised Dystonia

People aged 16 years and older with Generalised dystonia which is either primary or secondary and who meet all the general criteria in section 2.1.1, and have one or more of the following:

- have not had an adequate response to botulinum toxin treatment
- have failed to tolerate botulinum toxin treatment
- require such large or frequent treatments with botulinum toxin as to make such treatment impractical
- are unsuitable for botulinum toxin treatment.

**and** meet the following criteria:

- have an established clinical diagnosis of generalised Dystonia as determined by a consultant neurologist, **and**
- exhibit focal or generalised dystonia of sufficient severity to compromise quality of life, **and**
- the dystonia is the primary cause of the disability, **and**
- there are no significant postural defects or significant fixed joint deformities, **and**
- have had a 2 month trial of appropriate dose levodopa to exclude Dopa Responsive Dystonia or not felt to be clinically indicated, **and**
- 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 tolerated or applicable best medical therapy (BMT) post assessment by a movement disorder consultant neurologist, **and**
- have a diagnosis of psychogenic dystonia should have been considered and excluded as far as clinically possible.

### 2.1.4 Focal and Segmental Dystonia

People aged 16 years and older that meet all of the general criteria in section 2.1.1, **and**:

- have an established clinical diagnosis of focal or segmental dystonia e.g. focal and segment forms of dystonia as determined by a consultant neurologist, **and**
- exhibit focal or segmental dystonia of sufficient severity to compromise quality of life, **and**
- the dystonia is the primary cause of the disability, **and**
- there are no significant postural defects or significant fixed joint deformities.

### 2.1.5 Cervical Dystonia

People aged 16 years and older that meet all of the general criteria in section 2.1.1, **and**:

- have an established diagnosis of cervical dystonia as determined by a consultant neurologist, **and**
- are 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), **and**
- exhibit cervical dystonia of sufficient severity to compromise quality of life, **and**
- the dystonia is the primary cause of the disability, **and**
- there are no significant postural defects or significant fixed joint deformities.

**and** one or more of the following:

- Have not had an adequate response to botulinum toxin treatment.
- Have failed to tolerate botulinum toxin treatment.
- Require such large or frequent treatments with botulinum toxin as to make such treatment impractical.
- Are unsuitable for botulinum toxin treatment.

### 2.1.6 Status Dystonicus

People aged 16 years and older that meet all of the general criteria in section 2.1.1, **and**:

- have been seen by a consultant neurologist (paediatric) and neurosurgeon to arrive at final decision, **and**
- have severe and frequent episodes of generalised dystonia which require urgent hospital admission with or without systemic complications (e.g. respiratory or renal compromise, rhabdomyolysis), **and**

- there is a presence of an established diagnosis for the underlying disease resulting in status for example primary / secondary dystonia and a cause for secondary if possible, **and**
- any underlying trigger for the status dystonicus has been identified and treated if this is possible, **and**
- the condition is refractory to medical management which includes sedation, muscle relaxation and supportive treatment, **and**
- are fit to undergo deep brain stimulation surgery under general anaesthesia without contra-indication to DBS surgery (significant brain atrophy or pathology in anatomical area targeted for dystonia).

### **2.1.7 Essential Tremor or Dystonic Tremor:**

People aged 16 years and older that meet all of the general criteria in section 2.1.1, **and**:

- have an established diagnosis of essential tremor or dystonic tremor as determined by a consultant neurologist, **and**
- the tremor significantly impair activities of daily living to an extent that impairs quality of life, **and**
- are fit to under DBS surgery under general anaesthesia (assessed by an anaesthetic opinion) with no contra-indications for surgery (e.g. sepsis/ coagulopathy), **and**
- 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, **and**
- the treatment of the tremor is likely to produce a functionally useful improvement in disability.

### **2.1.8 For Essential Tremor**

People aged 16 years and older that meet all of the general criteria in section 2.1.1, **and**:

- Beta blockers have been tried and failed or not tolerated or not applicable, **and / or**
- Primidone has been tried and failed or not tolerated or not applicable, **and /or**
- Gabapentin has been tried and failed or not tolerated or not applicable.

### **2.1.9 For Dystonic Tremor**

People aged 16 years and older that meet all of the general criteria in section 2.1.1, **and**:

- anticholinergics have been tried and failed or not tolerated or not applicable.

### **2.1.10 Mid Brain Tremor**

People aged 16 years and older that meet all of the general criteria in section 2.1.1, **and**:

- have an established diagnosis of mid brain tremor as determined by a consultant neurologist, **and**
- the 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, **and**
- are fit to under DBS surgery under general anaesthesia (by anaesthetic opinion) with no contra-indications for surgery (e.g. sepsis/coagulopathy), **and**
- 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, **and**
- medication should have been tried and failed, or not tolerated or applicable, **and**
- an MRI has been performed which does not demonstrate pathological involvement/destruction of the target site for DBS.

**and** one of the following:

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

## **2.2 Exclusion Criteria**

WHSSC does not fund DBS for any of the following indications:

- Neuropathic pain
- Refractory Epilepsy (all ages)
- Cluster headache
- Central Post Stroke Pain
- Refractory Tourette Syndrome (adults)
- Psychiatric disorders (e.g. severe depression, psychosis)
- Patient with evidence of dementia or current serious non drug related psychopathology.

## **2.3 Continuation of Treatment**

Healthcare professionals are expected to review a patient's health at regular intervals to ensure they are demonstrating an improvement to their health due to the treatment being given.

If no improvement to a patient's health has been recorded then clinical judgement on the continuation of treatment must be made by the treating healthcare professional.

If DBS is not provided following a referral to a specialist centre the patient could suffer adverse psychological effects, therefore, psychological support should be made available locally for the patient.

## **2.4 Acceptance Criteria**

The service outlined in this specification is for patients above the age of 16 and are ordinarily resident in Wales, or otherwise the commissioning responsibility of the NHS in Wales. This excludes patients who whilst resident in Wales, are registered with a GP practice in England, but includes patients resident in England who are registered with a GP Practice in Wales.

## **2.5 Patient Pathway (Annex i)**

Referrals and requests for funding DBS surgery should be made by consultant neurosurgeons, consultant neurologists or consultant physicians with a special interest in Parkinson's disease. There is also a need for clinical neuropsychologists to help inform the decision-making process.

All referrals for DBS are managed through a clinical gatekeeping process. If the referring clinician believes that the patient meets the access criteria stipulated in section 2.1, they should contact the designated gatekeeper for their area as set out in Annex ii.

The referral should be accompanied by a completed proforma (see annex iii) with copies of relevant clinic letters and clinical history to support the referral. The role of the gatekeeper is to ensure that the referral meets the agreed criteria.

## **2.6 Designated Centres**

### **South, Mid and West Wales – Gatekeeper**

Neurology department,  
Aneurin Bevan University Health Board  
Nevill Hall Hospital  
Abergavenny  
NP7 7EG

### **North Bristol Trust – South Wales Referrals**

Southmead Hospital  
Southmead Road  
Westbury-on-Trym  
Bristol BS10 5NB

### **North Wales – Gatekeeper and Treatment**

Walton Centre NHS Foundation Trust  
Lower Land  
Fazakerley

### **Powys – via South, Mid and West Wales Gatekeeper**

Queen Elizabeth Hospital Birmingham  
Neurology Department  
Mindelsohn Way,  
Edgbaston,  
Birmingham,  
B15 2WB

## **2.7 Exceptions**

If the patient does not meet the criteria for treatment as outlined in this policy, an Individual Patient Funding Request (IPFR) can be submitted for consideration in line with the All Wales Policy: Making Decisions on Individual Patient Funding Requests. The request will then be considered by the All Wales IPFR Panel.

If the patient wishes to be referred to a provider outside of the agreed pathway, and IPFR should be submitted.

Further information on making IPFR requests can be found at: [Welsh Health Specialised Services Committee \(WHSSC\) | Individual Patient Funding Requests](#)

## **2.8 Clinical Outcome and Quality Measures**

The Provider must work to written quality standard and provide monitoring information to the lead purchaser. North Bristol NHS Trust has developed a robust MDT structure and patient evaluation methods which has been used as a framework for the NHS Executive to set standards for the designation of centres of excellence for Functional Neurosurgery across the UK.

## **2.9 Responsibilities**

Referrers should:

- inform the patient that this treatment is not routinely funded outside the criteria in this policy, and
- refer via the agreed pathway.

Clinician considering treatment should:

- discuss all the alternative treatment with the patient
- advise the patient of any side effects and risks of the potential treatment
- inform the patient that treatment is not routinely funded outside of the criteria in the policy, and
- confirm that there is contractual agreement with WHSSC for the treatment.

In all other circumstances submit an IPFR request.



### **3. Evidence**

WHSSC is committed to regularly reviewing and updating all of its clinical commissioning policies based upon the best available evidence of both clinical and cost effectiveness.

#### **3.1 References**

The evidence to support the recommendations within the policy are derived from the documents listed in 1.7.

#### **3.2 Date of Review**

This document is scheduled for review in 2023 where we will check if any new evidence is available. If no new evidence or intervention is available the review date will be progressed.

If an update is carried out the policy will remain extant until the revised policy is published.

## **4. Equality Impact and Assessment**

The Equality Impact Assessment (EQIA) process has been developed to help promote fair and equal treatment in the delivery of health services. It aims to enable Welsh Health Specialised Services Committee to identify and eliminate detrimental treatment caused by the adverse impact of health service policies upon groups and individuals for reasons of race, gender re-assignment, disability, sex, sexual orientation, age, religion and belief, marriage and civil partnership, pregnancy and maternity and language (Welsh).

This policy has been subjected to an Equality Impact Assessment.

The Assessment demonstrates the policy is robust and there is no potential for discrimination or adverse impact. All opportunities to promote equality have been taken.

## **5. Putting Things Right: Raising a Concern**

### **5.1 Raising a Concern**

Whilst every effort has been made to ensure that decisions made under this policy are robust and appropriate for the patient group, it is acknowledged that there may be occasions when the patient or their representative are not happy with decisions made or the treatment provided.

The patient or their representative should be guided by the clinician, or the member of NHS staff with whom the concern is raised, to the appropriate arrangements for management of their concern.

If a patient or their representative is unhappy with the care provided during the treatment or the clinical decision to withdraw treatment provided under this policy, the patient and/or their representative should be guided to the LHB for [NHS Putting Things Right](#). For services provided outside NHS Wales the patient or their representative should be guided to the [NHS Trust Concerns Procedure](#), with a copy of the concern being sent to WHSSC.

### **5.2 Individual Patient Funding Request (IPFR)**

If the patient does not meet the criteria for treatment as outlined in this policy, an Individual Patient Funding Request (IPFR) can be submitted for consideration in line with the All Wales Policy: Making Decisions on Individual Patient Funding Requests. The request will then be considered by the All Wales IPFR Panel.

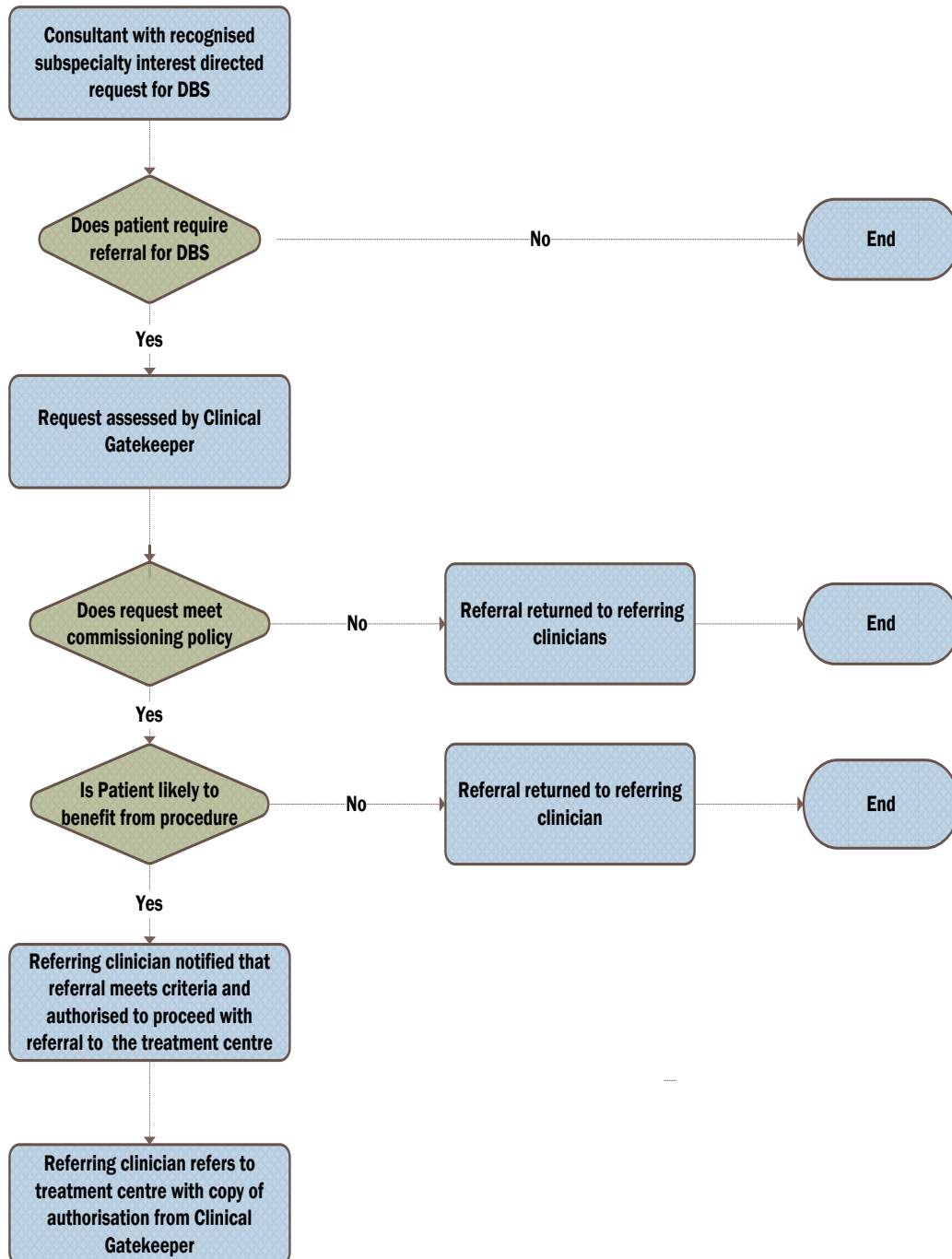
If an IPFR is declined by the Panel, a patient and/or their NHS clinician has the right to request information about how the decision was reached. If the patient and their NHS clinician feel the process has not been followed in accordance with this policy, arrangements can be made for an independent review of the process to be undertaken by the patient's Local Health Board. The ground for the review, which are detailed in the All Wales Policy: Making Decisions on Individual Patient Funding Requests (IPFR), must be clearly stated

If the patient wishes to be referred to a provider outside of the agreed pathway, an IPFR should be submitted.

Further information on making IPFR requests can be found at: [Welsh Health Specialised Services Committee \(WHSSC\) | Individual Patient Funding Requests](#)

## Annex i Patient Pathway

### Current Referral Pathway



## Annex ii Checklist

### Specialised Services Commissioning Policy – CP28, Deep Brain Stimulation.

The following should be completed for every patient to whom the policy applies:

- Where the patient meet the criteria **and** the procedure is included in the contract **and** the referral is received by an agreed centre, the form should be completed and retained by the receiving centre for audit purposes.

#### North Wales

Patients in North Wales receive DBS surgery from the Walton Centre Foundation Trust, and the referral and gatekeeping functions are undertaken as part of the wider neurology service commissioned from Trust.

As part of the commissioning arrangements with the Trust, all referrals are managed within the neurology service, and subsequent to assessment against the criteria are referred as appropriate on to the movement disorders service for assessment for Deep Brain Stimulation.

#### South Wales

Patients in South Wales receive DBS surgery from the North Bristol NHS Trust<sup>6</sup>. There are no commissioning arrangements in place for the neurology service provided by North Bristol NHS Trust, and therefore gatekeeping function is undertaken by a Consultant Neurologist based in the service provided by the Aneurin Bevan Health Board.

If a clinician is considering a referral into the North Bristol service they must first contact the South Wales gatekeeper for approval to refer. The referring clinician must provide a copy of the appropriate referral proforma together with copies of relevant clinic letters and clinical history. If the referral meets the criteria, the clinical gatekeeper will approve the referral, and will provide the referrer with a stamped letter of authorisation so that the referring clinician can proceed with the referral to the treatment centre.

The patient meets the criteria **and** is received at an agreed centre, but the procedure is not included in the contract. The checklist must be completed and submitted to WHSSC for prior approval to treatment.

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<sup>6</sup> <https://www.nbt.nhs.uk/our-services/a-z-services/functional-neurosurgery> Functional Neurosurgery

The patient meets the criteria but wishes to be referred to a non-contracted provider. An Individual Patient Funding Request (IPFR) Form must be completed and submitted to WHSSC for consideration.

If the patient does not meet the criteria for treatment as outlined in this policy, an Individual Patient Funding Request (IPFR) can be submitted for consideration in line with the All Wales Policy: Making Decisions on Individual Patient Funding Requests. The request will then be considered by the All Wales IPFR Panel.

### **All Wales**

The receiving clinician at the both treatment centres will assess the patient using the criteria as set out in annex iv. If the patient meets the criteria, the receiving clinician at the treatment centre should complete the criteria based access form and submit to the WHSSC patient care team for approval through the prior approvals process.

If the referring clinician believes that there are exceptional grounds for treatment an Individual Patient Funding Request (IPFR) can be made to WHSSC under the All Wales Policy for Making Decisions on Individual Patient Funding Requests (IPFR).

	<b><i>Clinical gatekeeper</i></b>	<b><i>Treatment Centre</i></b>
<b>North Wales</b>	Dr Dinesh Damodaran, Consultant Neurologist, Divisional Clinical Director (Neurology), Walton Centre NHS Foundation Trust, Liverpool, L9 7LJ	Walton Centre NHS Foundation Trust
<b>Mid, West and South Wales</b>	Dr Kenneth Dawson, Consultant Neurologist Aneurin Bevan University Health Board, Nevill Hall Hospital, Abergavenny, NP7 7EG	Aneurin Bevan University Health Board

If the patient wishes to be referred to a provider out of the agreed pathway, an IPFR should be submitted.

### Annex iii Deep Brain Stimulation Gatekeeper Referral Proforma

Patient Medical History Pro Forma		
<b>1. Patient initials:</b>	<b>2. Date of Birth:</b>	<b>4. Postcode:</b>
	<b>3. Gender:</b>	<b>5. NHS No:</b>
<b>6. Diagnosis</b>		
<b>7. Summary of History</b>		
<b>Relevant Medical History</b>		
<b>General Health (physical and mental)</b>		
<b>Current medication</b>		
<b>Degree of symptom control on current medication</b>		
<b>Impact of condition on activities of daily living and quality of life</b>		
<b>Signed</b> _____		
<b>Name</b> _____		
<b>Date</b> _____		

**Please return this form together with copies of relevant clinic letters and clinical history to:**

Clinical Gatekeeper

## Annex iv Deep Brain Stimulation Prior Approval Proforma

Patient Medical History Pro Forma		
<b>1. Patient initials:</b>	<b>2. Date of Birth:</b>	<b>4. Postcode:</b>
	<b>3. Gender:</b>	<b>5. NHS No:</b>
<i>Please tick the boxes and sign to confirm the patient meets the appropriate criteria for their specific clinical presentation.</i>		
<b>General</b>	<input type="checkbox"/> Patient is in good general health and are considered to have a life expectancy of 5 or more years as assessed by a detailed medical history and post liaison with other professionals, <b>and</b> <input type="checkbox"/> Symptoms are severe enough to significantly compromise quality of life and the activities of daily living, <b>and</b> <input type="checkbox"/> Patient has no evidence of dementia or current serious non drug related psychopathology, <b>and</b> <input type="checkbox"/> The patient is fit to undergo DBS surgery under general anaesthesia with no contra-indications for surgery (e.g. sepsis/coagulopathy)	
<b>Parkinson's Disease</b>	Meet all of the general criteria <b>and</b> all the following criteria: - <input type="checkbox"/> Have an established diagnosis of Parkinson's Disease as assessed by the UK Parkinson's Disease Society Brain Bank Criteria <input type="checkbox"/> Have symptoms of motor complications severe enough to significantly compromise function and quality of life -on/off fluctuations; L-dopa induced dyskinesias or medication resistant functionally impairing tremor. <input type="checkbox"/> All other medical and surgical interventions have been considered and exhausted or are not felt to be applicable <input type="checkbox"/> Patient is free from clinically significant cognitive impairment	
<b>Generalised Dystonia</b>	Meet all of the general criteria <b>and</b> all the following criteria: - Please tick <b>one</b> of the two options <input type="checkbox"/> The generalised dystonia is felt to be primary <input type="checkbox"/> The generalised dystonia is felt to be secondary  <b>and</b> one or more of the following: <input type="checkbox"/> Did not have had an adequate response to botulinum toxin treatment <input type="checkbox"/> Failed to tolerate botulinum toxin treatment <input type="checkbox"/> Requires such large or frequent treatments with botulinum toxin as to make such treatment impractical <input type="checkbox"/> Unsuitable for botulinum toxin treatment.  <b>and</b> meet all of the following criteria:-	



	<ul style="list-style-type: none"> <li><input type="checkbox"/> An established clinical diagnosis of generalised Dystonia as determined by a consultant neurologist</li> <li><input type="checkbox"/> Exhibit focal or generalised dystonia of sufficient severity to compromise quality of life</li> <li><input type="checkbox"/> The dystonia is the primary cause of the disability</li> <li><input type="checkbox"/> There are no significant postural defects or significant fixed joint deformities</li> <li><input type="checkbox"/> Has had a 2 month trial of appropriate dose levodopa to exclude dopa responsive dystonia or not felt to be clinically indicated</li> <li><input type="checkbox"/> 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 tolerated or applicable best medical therapy (BMT) post assessment by a movement disorder consultant neurologist</li> <li><input type="checkbox"/> A diagnosis of psychogenic dystonia should have been considered and excluded as far as clinically possible</li> </ul>
<p><b>Focal or Segmental Dystonia</b></p>	<p>Meet all of the general criteria <b>and</b> all of the following criteria: -</p> <ul style="list-style-type: none"> <li><input type="checkbox"/> An established clinical diagnosis of focal or segmental dystonia as determined by a consultant neurologist</li> <li><input type="checkbox"/> Exhibit focal or segmental dystonia of sufficient severity to compromise quality of life</li> <li><input type="checkbox"/> The dystonia is the primary cause of the disability</li> <li><input type="checkbox"/> There are no significant postural defects or significant fixed joint deformities</li> </ul>
<p><b>Cervical Dystonia</b></p>	<p>Meet all of the general criteria <b>and</b> the following criteria: -</p> <ul style="list-style-type: none"> <li><input type="checkbox"/> An established diagnosis of cervical dystonia as determined by a consultant neurologist</li> <li><input type="checkbox"/> 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).</li> <li><input type="checkbox"/> Exhibit cervical dystonia of sufficient severity to compromise quality of life</li> <li><input type="checkbox"/> The dystonia is the primary cause of the disability</li> <li><input type="checkbox"/> There are no significant postural defects or significant fixed joint deformities</li> </ul> <p>Please tick <b>one or more</b> of the following four boxes:</p> <ul style="list-style-type: none"> <li><input type="checkbox"/> Did not have had an adequate response to botulinum toxin treatment</li> <li><input type="checkbox"/> Failed to tolerate botulinum toxin treatment</li> <li><input type="checkbox"/> Requires such large or frequent treatments with botulinum toxin as to make such treatment impractical</li> </ul>

	<input type="checkbox"/> Unsuitable for botulinum toxin treatment.
<b>Status Dystonicus</b>	<p>Meet all of the general criteria <b>and</b> the following criteria:-</p> <ul style="list-style-type: none"> <li><input type="checkbox"/> Patient is seen by a consultant neurologist (adults/paediatric) and neurosurgeon to arrive at final decision</li> <li><input type="checkbox"/> 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, rhabdomyolysis)</li> <li><input type="checkbox"/> Presence of an established diagnosis for the underlying disease resulting in status for example primary / secondary dystonia and a cause for secondary if possible</li> <li><input type="checkbox"/> Any underlying trigger for the status dystonicus has been identified and treated if this is possible.</li> <li><input type="checkbox"/> Patient's condition is refractory to medical management which includes sedation, muscle relaxation and supportive treatment.</li> <li><input type="checkbox"/> Patient is fit to undergo deep brain stimulation surgery under general anaesthesia without contra-indication to DBS surgery (significant brain atrophy or pathology in anatomical area targeted for dystonia)</li> </ul>
<b>Essential or Dystonic Tremor</b>	<p>Meet all of the general criteria <b>and</b> the following criteria:-</p> <ul style="list-style-type: none"> <li><input type="checkbox"/> An established diagnosis of essential tremor or dystonic tremor as determined by a consultant neurologist</li> <li><input type="checkbox"/> Tremor sufficient to significantly impair activities of daily living to an extent that impairs quality of life</li> <li><input type="checkbox"/> The patient is fit to under DBS surgery under general anaesthesia (assessed by an anaesthetic opinion) with no contra-indications for surgery (e.g. sepsis/ coagulopathy)</li> <li><input type="checkbox"/> 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.</li> <li><input type="checkbox"/> Treatment of tremor is likely to produce a functionally useful improvement in disability.</li> </ul> <p><b>For Essential Tremor</b> please tick the following four boxes.</p> <ul style="list-style-type: none"> <li><input type="checkbox"/> Beta blockers have been tried and failed or not tolerated or not applicable <b>and/ or</b></li> <li><input type="checkbox"/> Primidone has been tried and failed or not tolerated or not applicable <b>and / or</b></li> <li><input type="checkbox"/> Gabapentin has been tried and failed or not tolerated or not applicable</li> </ul> <p><b>For Dystonic Tremor</b> please tick the following box:</p>

	<input type="checkbox"/> Anticholinergics have been tried and failed or not tolerated or not applicable
<b>Mid Brain Tremor</b>	<p>Meet all of the general criteria <b>and</b> the following criteria:</p> <ul style="list-style-type: none"> <li><input type="checkbox"/> An established diagnosis of mid brain tremor as determined by a consultant neurologist</li> <li><input type="checkbox"/> 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</li> <li><input type="checkbox"/> The patient is fit to under DBS surgery under general anaesthesia (by anaesthetic opinion) with no contra-indications for surgery (e.g. sepsis/coagulopathy).</li> <li><input type="checkbox"/> 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</li> <li><input type="checkbox"/> Medication should have been tried and failed, or not tolerated or applicable.</li> <li><input type="checkbox"/> An MRI has been performed which does not demonstrate pathological involvement /destruction of the target site for DBS.</li> </ul> <p>Please tick <b>one</b> of the below two boxes:</p> <ul style="list-style-type: none"> <li><input type="checkbox"/> The underlying diagnosis is multiple sclerosis (MS) and the predominant functional impairment is felt to be due to tremor rather than ataxia plus there is not sufficient spasticity, weakness, numbness or proprioceptive loss to prevent a return of function if tremor is removed</li> </ul> <p><b>OR</b></p> <ul style="list-style-type: none"> <li><input type="checkbox"/> The underlying diagnosis is infarction and there is not sufficient spasticity, weakness, numbness or proprioceptive loss to prevent a return of function if tremor is removed.</li> </ul>
<b>Signed</b> _____	
<b>Name</b> _____	
<b>Date</b> _____	

**Please return this form to:**

Patient Care Team  
 Welsh Health Specialised Services  
 Unit G1, Main Avenue  
 Treforest  
 Pontypridd  
 CF37 5YL

## **Annex v Codes**

### **ICD-10 Codes**

Code Category	Code	Description
ICD-10	G20X	Parkinson's Disease
ICD-10	G24	Dystonia
ICD-10	G250	Essential tremor
ICD-10	G35X	Multiple Sclerosis

### **OPCS 4 Codes**

Code Category	Code	Description
OPCS 4	A091	Implantation of DBS
OPCS 4	A095	Insertion of DBS Electrodes
OPCS 4	A093	Removal of DBS
OPCS 4	A092	Maintenance of DBS

## Annex vi Abbreviations and Glossary

### Abbreviations

<b>IPFR</b>	Individual Patient Funding Request
<b>WHSSC</b>	Welsh Health Specialised Services
<b>MDT</b>	Multi-disciplinary Team
<b>NICE</b>	National Institute for Health and Clinical Excellence

### Glossary

Definitions for these conditions has been taken from the NHS England Clinical Commissioning Policy for Deep Brain Stimulation.

**Parkinson's disease (PD)** <sup>7</sup> 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 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.

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<sup>7</sup> <https://www.england.nhs.uk/wp-content/uploads/2013/04/d03-p-b.pdf>