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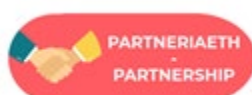
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Welsh Health Specialised  
Services Committee (WHSSC)

## **Specialised Services Policy Position Statement PP258**

**Transcranial magnetic resonance guided  
focused ultrasound (TcMRgFUS) thalamotomy  
for treatment of medication-refractory essential  
tremor for people aged 18 and over**

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## Document information

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## Contents

<b>Policy Statement</b> .....	4
Welsh Language .....	4
Decarbonisation .....	4
1. Introduction .....	6
1.1 Plain language summary .....	6
1.2 Aims and Objectives .....	6
1.3 Epidemiology .....	7
1.4 Current Treatment.....	7
1.6 What NHS Wales has decided.....	8
2. Criteria for Commissioning .....	9
2.1 Inclusion Criteria .....	9
2.2 Exclusion Criteria .....	9
2.3 Continuation of Treatment.....	10
2.4 Acceptance Criteria.....	10
2.5 Patient Pathway (Annex ii).....	10
2.6 Exceptions.....	11
2.7 Clinical Outcome and Quality Measures .....	11
2.8 Responsibilities .....	11
3. Documents which have informed this policy .....	13
4. Date of Review .....	14
5. Putting Things Right.....	15
5.1 Raising a Concern.....	15
5.2 Individual Patient Funding Request (IPFR) .....	15
6. Equality Impact and Assessment.....	16
Annex i Abbreviations and Glossary .....	17
Annex ii Patient Pathway .....	19

## **Policy Statement**

Welsh Health Specialised Services Committee (WHSSC) will commission Transcranial magnetic resonance guided focused ultrasound (TcMRgFUS) thalamotomy for the treatment of medication-refractory essential tremor for people aged 18 and over, in accordance with the criteria outlined in this document.

In creating this document WHSSC has reviewed the relevant guidance issued by NHS England and the National Institute of Health and Care Excellence (NICE) and has concluded that TcMRgFUS thalamotomy should be made available.

## **Welsh Language**

WHSSC is committed to treating the English and Welsh languages on the basis of equality, and endeavour to ensure commissioned services meet the requirements of the legislative framework for Welsh Language, including the [Welsh Language Act \(1993\)](#), the [Welsh Language \(Wales\) Measure 2011](#) and the [Welsh Language Standards \(No.7\) Regulations 2018](#).

Where a service is provided in a private facility or in a hospital outside of Wales, the provisions of the Welsh language standards do not directly apply but in recognition of its importance to the patient experience the referring health board should ensure that wherever possible patients have access to their preferred language.

In order to facilitate this WHSSC is committed to working closely with providers to ensure that in the absence of a Welsh speaker, written information will be offered and people have access to either a translator or 'Language-line' if requested. Where possible, links to local teams should be maintained during the period of care.

## **Decarbonisation**

WHSSC is committed to taking assertive action to reducing the carbon footprint through mindful commissioning activities. Where possible and taking into account each individual patient's needs, services are provided closer to home, including via digital and virtual access, with a delivery chain for service provision and associated capital that reflects the WHSSC commitment.

## **Disclaimer**

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

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, or Local Authority.

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

## **1. Introduction**

This Policy Position Statement has been developed for the planning and delivery of Transcranial Magnetic Resonance guided Focused Ultrasound (TCMRgFUS) thalamotomy for people aged 18 and over who are resident in Wales. The Policy Position Statement has been adapted from the [NHS England Commissioning Policy 'Transcranial magnetic resonance guided focused ultrasound thalamotomy for treatment of medication-refractory essential tremor \(adults\)'](#).

This service will only be commissioned by the Welsh Health Specialised Services Committee (WHSSC) and applies to residents of all seven Health Boards in Wales.

TcMRgFUS thalamotomy is recommended as a treatment option for the treatment of medication refractory essential tremor, in patients that are not eligible for deep brain stimulation, within the criteria set out in this document.

The policy is restricted to people aged 18 years and over as there is insufficient evidence to confirm safety in children.

### **1.1 Plain language summary**

Essential tremor (ET) is the term used to describe uncontrolled shaking movements in parts of the body – most commonly in the arms and hands with no other symptoms and no underlying cause. ET is the most common movement disorder and is more common with increasing age. It can be mild in some people but can be more severe and disruptive to daily activities in others. The cause of ET is not known but it is known to run in families with approximately 50% of people affected having a family history of the condition.

### **1.2 Aims and Objectives**

This Policy Position Statement aims to define the commissioning position of WHSSC on the use of TCMRgFUS thalamotomy for people with medication-refractory essential tremor.

The objectives of this policy are to:

- ensure commissioning for the use of TCMRgFUS thalamotomy is evidence based
- ensure equitable access to TCMRgFUS thalamotomy
- define criteria for people with medication-refractory essential tremor to access treatment
- improve outcomes for people with medication-refractory essential tremor.

### **1.3 Epidemiology<sup>1</sup>**

There are no reliable estimates of prevalence of essential tremor (ET). NHS England estimates 50-150 patients per year could be eligible for this treatment (3-10 in Wales).

Age onset of ET is bi-modal (peaks at aged 15 and 50 -70).

ET increases markedly with age, with a prevalence of:

- 4.6% in people above 65 years old affected
- 21.7% in people above 95 years old affected.

### **1.4 Current Treatment**

- Drug therapy is the first line therapy for ET. Drug therapy will stop working for between a quarter and half of patients and this is known as 'medication-refractory ET'. Surgical intervention is offered to patients whose symptoms are significant and severe and have not responded to medication.
- Deep brain stimulation (DBS) is a well-established surgical procedure that is currently commissioned for people with medication-refractory ET<sup>2</sup>. Electrodes are inserted into a specific area of the brain that is responsible for modifying movements. The area of the brain most commonly targeted to improve the tremor is the ventral intermediate (VIM) nucleus of the thalamus. DBS is effective at improving people's symptoms but the benefits of DBS tend to diminish over time.
- Stereotactic radiosurgery is a non-invasive technique using highly conformal radiotherapy delivered to the VIM nucleus.

### **1.5 Proposed Treatment**

Transcranial Magnetic Resonance guided Focused Ultrasound (TCMRgFUS) thalamotomy is a new procedure for the treatment of ET. This procedure uses focused ultrasound waves generated externally to the body that are directed to, and alter the function of the VIM nucleus to improve the tremor. This is undertaken under magnetic resonance imaging (MRI) guidance.

This is a non-invasive procedure that does not require the introduction or maintenance of hardware into the brain, avoiding the maintenance of the inserted hardware (i.e., battery replacement) and minimises the risk of bleeding within the skull, stroke and infection. Throughout the procedure, the patient is continuously monitored for changes in tremor. This can be

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<sup>1</sup> [Transcranial magnetic resonance guided focused ultrasound thalamotomy for treatment of medication refractory essential tremor \(adults\). NHS England Commissioning Policy \(2020\)](#)

<sup>2</sup> <https://whssc.nhs.wales/commissioning/whssc-policies/all-policy-documents/deep-brain-stimulation-cp28/>

performed as a day-case procedure and does not require the use of general anaesthesia.

### **1.6 What NHS Wales has decided**

WHSSC has reviewed the relevant guidance issued by NHS England and concluded that there is sufficient evidence to support commissioning of TcMRgFUS thalamotomy for medication-refractory essential tremor. WHSSC have concluded that the use of this intervention should be made available within the criteria set out in section 2.1.



## 2. Criteria for Commissioning

The Welsh Health Specialised Services Committee (WHSSC) approve funding of Transcranial Magnetic Resonance guided Focused Ultrasound (TcMRgFUS) thalamotomy for the treatment of medication-refractory essential tremor (ET) for people aged 18 and over, in-line with the criteria presented in this policy.

### 2.1 Inclusion Criteria

People aged 18 and over meeting all the following relevant criteria should be considered for TcMRgFUS thalamotomy for the treatment of medication refractory ET:

- People with medication-refractory tremor
- People who are not eligible for DBS under [WHSSC Commissioning Policy for DBS; CP28](#)
- People with a diagnosis of either a postural tremor or an intention tremor of grade 3 or 4 in the target upper limb (scored using the Clinician Rating of Severity of Tremor (CRST) Part A - *see Appendix A of NHS England Clinical Commissioning Policy*<sup>3</sup>)
- A score of 2 or above in any one of its items in the CRST Part C, (items 16-23) (*see Appendix A of NHS England Clinical Commissioning Policy*<sup>3</sup>)
- Tremor sufficient to significantly impair activities of daily living to an extent that it impairs quality of life supported by a clinical tremor rating score. 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.

Patients may also be considered with bilateral medication-refractory essential tremor, provided that treatment is only considered on one side.

### 2.2 Exclusion Criteria

The policy is restricted to people aged 18 years and over as there is insufficient evidence to confirm safety in children.

People who meet any of the following criteria are not suitable for TcMRgFUS thalamotomy for treatment of essential tremor:

- People who do not have a diagnosis of essential tremor
- People who are receiving or are currently eligible to receive DBS

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<sup>3</sup> [Transcranial magnetic resonance guided focused ultrasound thalamotomy for treatment of medication refractory essential tremor \(adults\). NHS England Commissioning Policy \(2020\)](#)

- People with a diagnosis of Parkinson’s disease
- People unable to undergo an MRI scan.

### **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.

### **2.4 Acceptance Criteria**

The service outlined in this Policy proposal is for patients 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 ii)**

Patients with unilateral medication-refractory tremor are referred into the neurology outpatient department where they are seen by a movement disorder specialist neurologist.

Patients may also be considered with bilateral medication-refractory essential tremor, provided that treatment is only considered on one side. They have routine (simple) blood tests, along with an MRI of the head.

Patients should be discussed by the MDT (which should include a movement disorder neurologist, neuroradiologist, functional neurosurgeon and appropriate specialist nursing, neuropsychological and neuropsychiatric input). If medication-refractory tremor is diagnosed, baseline tremor severity should be assessed with a Clinician Rating of Severity of Tremor (CRST) score (see Appendix A of NHS England Clinical Commissioning Policy)<sup>4</sup>.

If the patient meets the eligibility criteria, and does not meet any of the exclusion criteria, they are consented and booked in for the procedure, which is completed as a day case. The procedure is performed in an MRI-guided focused ultrasound system. The patients are then followed up routinely by the movement disorder specialist neurologist.

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<sup>4</sup> [Transcranial magnetic resonance guided focused ultrasound thalamotomy for treatment of medication refractory essential tremor \(adults\). NHS England Commissioning Policy \(2020\)](#)

This service is only provided at two designated centres in NHS England.

- The Walton Centre  
Lower Lane  
Liverpool  
L9 7LJ
- St. Mary Hospital  
Praed Street  
London  
W2 1NY

## **2.6 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 (see section 5.2).

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

## **2.7 Clinical Outcome and Quality Measures**

The Provider must work to written quality standards and provide monitoring information to the lead commissioner.

The centre must enable the patient's, carer's and advocate's informed participation and to be able to demonstrate this. Provision should be made for patients with communication difficulties.

## **2.8 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 an IPFR must be submitted.

### **3. Documents which have informed this policy**

The following documents have been used to inform this policy:

- **WHSSC policies and service specifications**
  - [CP28, Deep Brain Stimulation, August 2020](#)
- **National Institute of Health and Care Excellence (NICE) guidance**
  - National Institute for Health and Care Excellence (NICE). Deep Brain stimulation for tremor and dystonia (excluding Parkinson’s disease). NICE interventional procedure guidance 188 (2006). <https://www.nice.org.uk/guidance/IPG188>.
  - National Institute for Health and Care Excellence (NICE). Unilateral MRI-guided focused ultrasound thalamotomy for treatment-resistant essential tremor. NICE Interventional Procedures Guidance 617 (2018) <https://www.nice.org.uk/guidance/IPG617>.
- **NHS England policies**
  - NHS England Clinical Commissioning Policy. Transcranial magnetic resonance guided focused ultrasound thalamotomy for treatment of medication-refractory essential tremor (adults). Reference 200203P [1904-transcranial-magnetic-resonance-guided-focused-ultrasound-thalamotomy-for-treatment-of-medication-refract.pdf \(england.nhs.uk\)](#)
  - NHS England Clinical Commissioning Policy. Deep Brain Stimulation (DBS) in Movement Disorders. Reference NHSCB/D03/P/b. NHS England 2013. <https://www.england.nhs.uk/wp-content/uploads/2018/07/DBS-for-MD.pdf>.

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

- **NHS Wales**
  - All Wales Policy: [Making Decisions in Individual Patient Funding requests](#) (IPFR).

#### **4. Date of Review**

This document is scheduled for review in 2026 when 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.

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## **5. Putting Things Right**

### **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](#)

## **6. 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.



## **Annex i Abbreviations and Glossary**

### **Abbreviations**

<b>IPFR</b>	Individual Patient Funding Request
<b>WHSSC</b>	Welsh Health Specialised Services
<b>ET</b>	Essential Tremor
<b>TcMRgFUS</b>	Transcranial magnetic resonance guided focused ultrasound

### **Glossary**

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

An IPFR is a request to Welsh Health Specialised Services Committee (WHSSC) to fund an intervention, device or treatment for patients that fall outside the range of services and treatments routinely provided across Wales.

#### **Welsh Health Specialised Services Committee (WHSSC)**

WHSSC is a joint committee of the seven local health boards in Wales. The purpose of WHSSC is to ensure that the population of Wales has fair and equitable access to the full range of Specialised Services and Tertiary Services. WHSSC ensures that specialised services are commissioned from providers that have the appropriate experience and expertise. They ensure that these providers are able to provide a robust, high quality and sustainable services, which are safe for patients and are cost effective for NHS Wales.

#### **Essential Tremor**

A common neurological disorder that causes involuntary, repetitive movements of body part, often the arms or hands.

#### **Focused Ultrasound**

Non-invasive intervention using ultrasonic energy to target tissue deep in the body without incisions or radiation

#### **Magnetic resonance imaging**

Medical imaging technique using strong magnetic fields and radio waves to generate images of the body.

#### **Medication refractory**

Non response to two medications (one of which is the first line treatment – propranolol or primidone).

### **Thalamus**

The thalamus is a large egg-shaped mass of grey matter present in diencephalon, a part of the forebrain. The Thalamus is involved in sensory as well as motor functions of the brain.

### **Thalamotomy**

The precise destruction of a tiny area of brain called the thalamus.

## Annex ii Patient Pathway

