

Integrated Impact Assessment Report for Clinical Commissioning Policies

Policy Reference Number	1904
Policy Title	Transcranial magnetic resonance guided focused ultrasound thalamotomy for treatment of medication-refractory essential tremor (adults)
Proposal	<u>for routine commission</u> (ref A3.1)

Integrated Impact Assessment – Index

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About this Impact Assessment: instructions for completion and explanatory notes

- Each section is divided into themes with each theme setting out a number of questions.
- All figures should be provided up to 5 years only.
- The cost per patient methodology is impact against Year 0 rather than incrementally against the previous year.

- All questions are answered by selecting a drop-down option or including free text.
- Free text boxes are provided to enable succinct relevant commentary to be added which explains the rationale for response or assumption. Please limit responses to 3 sentences of explanatory text.
- Data in this document is either drawn from one of the relevant policy documents or a source for the information is provided.
- Where assumptions are included where data is not available, this is specified.
- A bespoke financial model should be developed unless agreed otherwise. This will be worked up against a checklist of inputs/considerations. This will include the approach to regional allocations which will also be outlined in the Commissioning Plan.

Section A - Activity Impact

A1 Activity

To be completed by the Clinical Policy Team

A1.1 Provide the number of patients eligible for the treatment. If different, also provide the number of patients accessing treatment.

Include OPCS codes where applicable.

150

Source: Policy proposition epidemiology section

Please specify

A2 Existing Patient Pathway (complete where additional information outside the policy proposition is likely to be beneficial)

To be completed by the Clinical Policy Team

A2.1 **Existing pathway:** Describe the relevant currently routinely commissioned:

- Treatment or intervention
- Patient pathway
- Eligibility and/or uptake estimates.

Currently routinely commissioned treatment for medication refractory essential tremor (ET) where the patient is ineligible for deep brain stimulation (DBS) is medication (propranolol, primidone, topiramate, gabapentin and benzodiazepines). Patient pathway: essential tremor is diagnosed by either a GP or movement disorder specialist, the patient is scored on a rating scale (such as clinical rating scale for tremor, CRST) and can be offered medication. Around 25-55% of patients with ET are refractory to medication. These patients can be assessed for eligibility for DBS, a surgical procedure performed by neurosurgeons, however it is estimated that 15% of patients would not be eligible for DBS.

Source: Policy proposition inclusion criteria and patient pathway

<p>A2.2 What percentage of the total eligible population is expected to:</p> <ul style="list-style-type: none"> a) Be clinically assessed for treatment b) Choose to initiate treatment c) Comply with treatment 	<p>If not known, please specify</p> <ul style="list-style-type: none"> a) 40% b) 100% c) ~23% <p>Source: <i>Louis et al. 2015, policy proposition epidemiology section, PWG</i></p>
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A3 Comparator (next best alternative treatment) Patient Pathway
(NB: comparator/next best alternative does not refer to current pathway but to an alternative option)
To be completed by the Clinical Policy Team

<p>A3.1 Next best comparator: Is there another ‘next best’ alternative treatment which is a relevant comparator? <i>If yes, describe relevant</i></p> <ul style="list-style-type: none"> • <i>Treatment or intervention</i> • <i>Patient pathway</i> • <i>Actual or estimated eligibility and uptake</i> 	<p><u>No</u></p> <p>Source: <i>N/A</i></p>
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<p>A3.2 What percentage of the total eligible population is estimated to:</p> <ul style="list-style-type: none"> a) Be clinically assessed for treatment b) Be considered to meet an exclusion criteria following assessment c) Choose to initiate treatment d) Comply with treatment e) Complete treatment? 	<p>Total estimated eligible or ‘Not applicable’.</p> <ul style="list-style-type: none"> a) Not applicable b) Not applicable c) Not applicable d) Not applicable e) Not applicable <p>Source: <i>N/A</i></p>
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A4 New Patient Pathway

<i>To be completed by the Clinical Policy Team</i>	
<p>A4.1 Specify the nature and duration of the proposed new treatment or intervention. For example, e.g patients receive a course of treatment over 6 cycles with the drug being administered via IV infusion on days 1 and 3 of each cycle.</p> <p>Include OPCS codes where applicable.</p>	<p><u>One off</u></p> <p><i>Source: Policy proposition proposed treatment</i></p>
A5 Treatment Setting <i>To be completed by the Clinical Policy Team</i>	
A5.1 How is this treatment delivered to the patient?	Procedure is booked in advance as a day case procedure that usually takes 4-5 hours within a specialist neuroradiologist centre with access to MR-guided ultrasound
A5.2 What is the current number of contracted providers for the eligible population by region?	Not currently commissioned but 1 Trust able to provide treatment.
A5.3 Does the proposition require a change of delivery setting or capacity requirements?	A further centre may be required this will be assessed as the policy is implemented.

A6 Coding

A6.1 Specify the datasets used to record the new patient pathway activity.

*expected to be populated for all commissioned activity

Select all that apply:

Aggregate Contract Monitoring *	<input checked="" type="checkbox"/>
Patient level contract monitoring	<input checked="" type="checkbox"/>
Patient level drugs dataset	<input type="checkbox"/>
Patient level devices dataset	<input type="checkbox"/>
Devices supply chain reconciliation dataset	<input type="checkbox"/>
Secondary Usage Service (SUS+)	<input checked="" type="checkbox"/>
Mental Health Services DataSet (MHSDS)	<input type="checkbox"/>
National Return**	<input type="checkbox"/>
Clinical Database**	<input type="checkbox"/>
Other**	<input type="checkbox"/>

**If National Return, Clinical database or other selected, please specify:

A6.2 Specify how the activity related to the new patient pathway will be identified.

Clinical coding:

ICD10 Diagnosis Code: G250 Essential tremor

OPCS Dominant Procedure Code: A032 Stereotactic ablation of tissue of thalamus

OPCS Additional Codes: Y115 Ultrasonic destruction of organ NOC and Y537 Approach to organ under magnetic resonance imaging control

A6.3 Identification Rules for Devices:

How are device costs captured?

Not applicable

<p>A6.4 Identification Rules for Activity: How are activity costs captured? (e.g., are there first and follow up outpatient appointments?)</p>	<p><u>Already correctly captured by an existing specialised service line (NCBPS code within the PSS Tool)</u> NCBPS08S ADULT SPECIALIST NEUROSCIENCES SERVICES: NEUROSURGERY</p>
<p>Section B - Service Impact <i>To be completed by the Lead Commissioner</i></p>	
<p>B1 Service Organisation</p>	
<p>B1.1 Describe how the service is currently organised? (i.e. tertiary centres, networked provision etc.)</p>	<p>Not currently commissioned <i>Source: required</i></p>
<p>B1.2 Will the proposition change the way the commissioned service is organised?</p>	<p><u>No</u> Please specify: Service will be commissioned from existing neuroscience centres <i>Source: required</i></p>
<p>B2 Geography & Access</p>	
<p>B2.1 How is the service currently accessed (e.g., self referral, referral from GP, secondary care, other)</p>	<p>Please specify: N/A – this is a new treatment option</p>
<p>B2.2 What impact will the new policy have on the sources of referral?</p>	<p><u>No impact</u> Please specify:</p>

<p>B2.3 Is the new policy likely to improve equity¹ of access?</p>	<p><u>Increase</u> Please specify: Patient cohort is not eligible for Deep Brain Stimulation <i>Source: Equalities Impact Assessment (NB. this should be completed during Clinical Build/Impact Assessment phases)</i></p>
<p>B2.4 Is the new policy likely to improve equality¹ of access and/or outcomes?</p>	<p><u>Increase</u> Please specify: <i>Source: Equalities Impact Assessment (NB. this should be completed during Clinical Build/Impact Assessment phases)</i></p>
<p>B3 Commissioning Responsibility</p>	
<p>B3.1 Is this service currently subject to, or planned for, place-based commissioning arrangements? (e.g. new service (NHS England responsibility), future CCG lead, devolved commissioning arrangements, STPs)</p>	<p><u>No change - NHSE</u> Please specify:</p>
<p style="text-align: center;">Section C - Finance Impact <i>To be completed by the Finance Lead with the exception of C1.2</i></p>	
<p>C1 Tariff/Pricing</p>	
<p>C1.1 How is the service contracted and/or charged? Only specify for the relevant section of the patient pathway</p>	<p><i>Select all that apply:</i></p> <hr/>

¹ <https://www.england.nhs.uk/wp-content/uploads/2016/02/nhse-specific-duties-equality-act.pdf>

	Drugs	Not separately charged – part of local or national tariffs	<input type="checkbox"/>
		Excluded from tariff – pass through	<input type="checkbox"/>
		Excluded from tariff – other	<input type="checkbox"/>
	Devices	Not separately charged – part of local or national tariffs	<input type="checkbox"/>
		Excluded from tariff (excluding HCTED programme) – pass through	<input type="checkbox"/>
		Excluded from tariff (excluding HCTED) – other	<input type="checkbox"/>
		Via HCTED model	<input type="checkbox"/>
	Activity	Paid entirely by National Tariffs	<input type="checkbox"/>
		Paid entirely by Local Tariffs	<input type="checkbox"/>
		Partially paid by National Tariffs	<input checked="" type="checkbox"/>
		Partially paid by Local Tariffs	<input type="checkbox"/>
		Part/fully paid under a Block arrangement	<input type="checkbox"/>
		Part/fully paid under Pass-Through arrangements	<input checked="" type="checkbox"/>
Part/fully paid under Other arrangements		<input type="checkbox"/>	
C1.2 Drug Costs <i>(to be completed by the Clinical Policy Team)</i>		N/A	
Where not included in national or local tariffs, list each drug or combination, dosage, quantity, list price including VAT if applicable and any other key information e.g. Chemotherapy Regime, homecare costs. Provide a basis for this assumption.			

<p>NB discounted prices or local prices must not be included as these are subject to commercial confidentiality and must not be disclosed.</p>	
<p>C1.3 Device Costs <i>(to be completed by LC)</i> Where not included in national or local tariff, list each element of the excluded device, quantity, list or expected price including VAT if applicable and any other key information. NB: Discounted prices or local prices must not be included as these are subject to commercial confidentiality and must not be disclosed.</p>	<p>N/A</p>
<p>C1.4 Activity Costs covered by National Tariffs <i>(to be completed by Finance)</i> List key HRG codes and descriptions, national tariffs (excluding MFF), volume and other key costs (e.g. specialist top up %). Include details of first and follow up outpatients appointment etc.</p>	<p>HRG AA71 Stereotactic Intracranial Radiosurgery, for Neoplasms or Other Neurological Conditions AA71A Stereotactic Intracranial Radiosurgery, for Neoplasms or Other Neurological Conditions, with CC Score 4+ £5,191 (c67% of patients) AA71B Stereotactic Intracranial Radiosurgery, for Neoplasms or Other Neurological Conditions, with CC Score 0-3 £4,955 (c33% of patients) Specialised Top Up for NCBPS08S 38.52% Weighted Cost excluding MFF £7,083</p>
<p>C1.5 Activity Costs covered by Local Tariff <i>(to be completed by Finance)</i> List all the HRGs (if applicable), HRG or local description, estimated average tariff, volume and any other key costs. Also indicate whether the Local Tariff(s) is/are newly proposed or established and if newly proposed how is has been derived, validated and tested.</p>	
<p>C1.6 Other Activity Costs not covered by National or Local Tariff <i>(to be completed by Finance)</i></p>	<p>Cost of Capital including Public Dividend Capital and assuming an asset life of 7 years £235,980 per year per provider</p>

Include descriptions and estimates of all key costs.	Cost of Maintenance @ 8% per year in Years 2-7 (Year 1 covered by warranty £127,680 per year per provider (excluding year 1))
C1.7 Are there any prior approval/notification mechanisms required either during implementation or permanently?	Please specify:
C2 Average Cost per Patient	
C2.1 What is the average cost per patient per year for 5 years, including follow-up where required?	<p>The average cost per patient over years 1-5 is £12,990.</p> <ul style="list-style-type: none"> • This is based on the cost of the procedure only as all other costs remain unchanged (patients with medication refractory tremor are all currently assessed via an MDT so TcMRgFUS would be a new treatment option). • The cost per patient is based on treating 650 patients over 5 years (50 in Year 1 and 150 per year in years 2-5). • A second provider is commissioned from year 2. • Maximum capacity per provider is 100 procedures per annum • The revenue costs of capital and maintenance are paid as pass-through <p>The additional cost per procedure if 3 centres were commissioned would be £1,989 (15.3%) due to the high capital cost of the kit required.</p> <p>The cost of £12,990 compares favourably to the cost of Deep Brain Stimulation (£25,430) which is commissioned for a different cohort of patients with Essential Tremor.</p>

C3 Overall Cost Impact of this Policy to NHS England											
<p>C3.1 Specify the budget impact of the proposal on NHS England in relation to the relevant pathway. Use list prices where drugs and devices are included. Commercial in confidence discounts are not included therefore the actual cost pressure may be lower than stated.</p>	<p><u>Cost pressure</u></p> <table border="1" data-bbox="1088 288 1603 560"> <tr> <td>Year 1</td> <td>£798.8k</td> </tr> <tr> <td>Year 2</td> <td>£1,814.7k</td> </tr> <tr> <td>Year 3</td> <td>£1,943.4k</td> </tr> <tr> <td>Year 4</td> <td>£1,943.4k</td> </tr> <tr> <td>Year 5</td> <td>£1,943.4k</td> </tr> </table> <p>The cost pressure is based on the optimum model of 2 providers.</p>	Year 1	£798.8k	Year 2	£1,814.7k	Year 3	£1,943.4k	Year 4	£1,943.4k	Year 5	£1,943.4k
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<p>C3.2 If the budget impact on NHS England cannot be identified set out the reasons why this cannot be measured.</p>	<p>N/A</p>										
<p>C3.3 If the activity is subject to a change of commissioning responsibility, from CCG to NHS England, has a methodology for the transfer of funds been identified, and calculated?</p>	<p>N/A</p>										
C4 Overall cost impact of this policy to the NHS as a whole											
<p>C4.1 Specify the budget impact of the proposal on other parts of the NHS.</p>	<p>Budget impact for CCGs:</p> <p><u>Cost saving</u></p> <p>There will be a small cost saving from a reduction in prescribed medication.</p>										

	<p>Budget impact for providers: <u>Cost neutral</u></p>										
<p>C4.2 Taking into account responses to C3.1 and C4.1, specify the budget impact to the NHS as a whole.</p>	<p><u>Cost pressure</u></p> <table border="1" data-bbox="1088 327 1603 598"> <tr> <td>Year 1</td> <td>£798.8k</td> </tr> <tr> <td>Year 2</td> <td>£1,814.7k</td> </tr> <tr> <td>Year 3</td> <td>£1,943.4k</td> </tr> <tr> <td>Year 4</td> <td>£1,943.4k</td> </tr> <tr> <td>Year 5</td> <td>£1,943.4k</td> </tr> </table>	Year 1	£798.8k	Year 2	£1,814.7k	Year 3	£1,943.4k	Year 4	£1,943.4k	Year 5	£1,943.4k
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Year 5	£1,943.4k										
<p>C4.3 Are there likely to be any costs or savings for non-NHS commissioners and/or public sector funders?</p>	<p><u>No</u> Please specify:</p>										
<p>C5 Funding</p>											
<p>C5.1 Where a cost pressure is indicated, state known source of funds for investment, where identified, e.g. decommissioning less clinically or cost-effective services.</p>	<p>CPAG Prioritisation Reserve</p>										
<p>C6 Financial Risks Associated with Implementing this Policy</p>											

C6.1 Describe the parameters used to generate the low, mid and high case scenarios for patient numbers and activity. Specify the range.	The number of procedures is being capped at 150. If activity reaches this threshold the policy will be reviewed.
C6.2 What scenario has been recommended and why? What would be the impact of a discounted scenario?	Due to the high capital outlay and annual maintenance costs the optimum model for service provision is 2 providers. The premium for a 3 rd provider would be an additional £355k per annum (15.3%). The assumed capacity per provider is c100 cases.
C7 Cost Profile	
C7.1 Factors which impact on costs	<p>Yes</p> <p>There is a high capital outlay for the service (c£1.6m) which will need to be sourced by the service provider. In order to share the cost risk between the commissioner and the 2 providers it is proposed to fund the revenue costs of capital and maintenance as pass through with a cost per procedure to cover all other treatment costs.</p>

The full integrated impact assessment should be used for all clinical commissioning policies and for policy statements which are proposing a for routine commissioning position. The rapid impact assessment template should be used for urgent policy statements and for policy statements which are proposing not for routine commissioning

Appendix A – Current Patient Population & Demography / Growth (for Public Health Lead to complete)

		Source	Please specify any further detail
Number of patients who meet the proposed commissioning criteria	[Enter number]		

and who would be treated if the proposal is approved per year.											
Age group for which the treatment is proposed according to the proposed criteria	<i>Adults/ Children/ Other: [please specify]</i>										
Age distribution of the patient population eligible according to the proposed criteria	<i>[Enter number]/ Not applicable</i>										
How is the population currently geographically distributed	<i>Evenly/unevenly</i> <table border="1" data-bbox="622 592 1106 810"> <tr> <td>North</td> <td></td> </tr> <tr> <td>Midlands & East</td> <td></td> </tr> <tr> <td>London</td> <td></td> </tr> <tr> <td>South</td> <td></td> </tr> </table>	North		Midlands & East		London		South		<i>Policy proposition (section 6)</i>	
North											
Midlands & East											
London											
South											
What are the growth assumptions for the disease / condition?		<i>Policy proposition (section 6)</i>									
Is there evidence of current inequalities in access to service or outcomes?											
Is there evidence that implementing the policy/service specification will improve current inequities of access or outcomes?											