NHS England

Integrated Impact Assessment Report for Clinical Commissioning Policies

Policy Reference Number	1903
Policy Title	Percutaneous Lt Atrial Catheter ablation for paroxysmal and persistent atrial fibrillation
Proposal	**for routine commission**(ref A3.1)

Integrated Impact Assessment – Index

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.	Approximately 3% of the adult population may develop AF. This gives a current approximate prevalence rate of 1.4 million people in England having AF (Adderley et al 2019). In 2018/2019, 7744 procedures were performed amongst this cohort of the population. *Source: SUS data FY 18-19.* <u>Dominant Procedure code for Lt Atrial Ablation for AF:</u> K621 Percutaneous transluminal ablation of pulmonary vein to left atrial conducting system K575 Percutaneous transluminal ablation of atrial wall NEC.
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	Ablation procedures are carried out in people that have non-permanent atrial fibrillation when medicines are not working or tolerated. Percutaneous left atrial catheter ablation is an ablation procedure that is carried out under sedation or a general anaesthetic. A small skin cut is made in the groin and thin tubes, known as catheters, are inserted into the femoral vein. These catheters are advanced into the upper chambers, the atria, of the heart under X-ray guidance. Certain parts of the left atrium are targeted with an energy source to isolate the areas that cause AF.

routinely commissioned:

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

Source: Service Specification A09/S/b Cardiology: Electrophysiology and Ablation Services Adult.

A2.2 What percentage of the total eligible population is expected to:

a) Be clinically assessed for treatment
b) Choose to initiate treatment
c) Comply with treatment

If not known, please specify: Difficult to quantify as some of these procedures will be repeat procedures making exact numbers unknown.

a) 100% (n=7744 procedures performed amongst the prevalent population of 1.3M). It is thought that approximately 16,000 patients (double actual procedures) will be assessed within clinic and 7744 receiving the procedure (FY 18-19 totals). Using SUS data it has been possible to calculate a repeat procedure rate (see below). The target group for this policy is those patients having 3 or more procedures. From the data, on average 284-325 procedures per year (average from actual data FY 15-16 to 19-20) are performed where 2 procedures have been performed previously.
b) 100%
c) 100%
d) NA

Profile of Patient's No of Procedures between 2015/16 to 2019/20 M9 (4.75 years)

					Annual Average 2015-201	
Count of Treatments	Total Procedures	% of Procedures	No of Patients	% of Patients	2015-2019 Average Per Year	% of Procedures
1	23,732	71.4%	23,732	84.3%	4,996	71.4%
2	7,942	23.9%	3,971	14.1%	1,672	23.9%
3	1,161	3.5%	387	1.4%	244	3.5%
4	164	0.5%	41	0.1%	35	0.5%
5	20	0.1%	4	0.0%	4	0.1%
6	6	0.0%	1	0.0%	1	0.0%
Unknown	194	0.6%	-	0.0%	41	0.6%
Total	**33,219**	**100.0%**	**28,136**	**100.0%**	**6,993**	**100.0%**

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*	
A3.1 **Next best comparator**: Is there another 'next best' alternative treatment which is a relevant comparator? *If yes, describe relevant* • *Treatment or intervention* • *Patient pathway* • *Actual or estimated eligibility and uptake*	**No** Not Applicable
A3.2 What percentage of the total eligible population is estimated to: a) Be clinically assessed for treatment	Not Applicable

b) Be considered to meet an exclusion criterion following assessment c) Choose to initiate treatment d) Comply with treatment e) Complete treatment?	
A4 New Patient Pathway *To be completed by the Clinical Policy Team*	
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	**<u>One off</u>** The policy covers two groups of patients, those who receive ablation for paroxysmal AF and those for persistent AF. The policy updates the current guidelines to apply exclusion criteria to procedures and provide additional guidance on the effectiveness patients receiving three or more ablations for persistent AF. Currently NICOR are reporting a reintervention rate of 23% from the population treated. Hence based upon a procedure rate of 7744 annually, 5% (n=284 -325) are for three or more procedures. NICOR provide data but currently are not able to calculate a repeat procedure rate in relation to how many interventions per patient. *Source:1.* https://www.nicor.org.uk/wp-content/uploads/2019/07/CRM-Report-2016-2017.pdf *2. SUS data extracted February 2019*

<table>
<tr><td>days 1 and 3 of each cycle.

Include OPCS codes where applicable.</td><td></td></tr>
<tr><td colspan="2">A5 Treatment Setting
To be completed by the Clinical Policy Team</td></tr>
<tr><td>A5.1 How is this treatment delivered to the patient?</td><td>In a specialist Cardiology Electrophysiology and Catheter Laboratory attached to a specialist centre.</td></tr>
<tr><td>A5.2 What is the current number of contracted providers for the eligible population by region?</td><td>
<table>
<tr><td>North West</td><td>5</td></tr>
<tr><td>North East and Yorkshire</td><td>5</td></tr>
<tr><td>Midlands</td><td>7</td></tr>
<tr><td>East of England</td><td>2</td></tr>
<tr><td>London</td><td>6</td></tr>
<tr><td>South East</td><td>5</td></tr>
<tr><td>South West</td><td>4</td></tr>
<tr><td>Total</td><td>34</td></tr>
</table>
</td></tr>
</table>

A5.3 Does the proposition require a change of delivery setting or capacity requirements?	*No*
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 * ☒ Patient level contract monitoring ☒ Patient level drugs dataset ☐ Patient level devices dataset ☐ Devices supply chain reconciliation dataset ☐ Secondary Usage Service (SUS+) ☒ Mental Health Services DataSet (MHSDS) ☐ National Return** ☒ Clinical Database** ☐

	Other** ☐ **If National Return, Clinical database or other selected, please specify: NICOR
A6.2 Specify how the activity related to the new patient pathway will be identified.	Procedure codes are already available for this procedure as it is routinely commissioned. However, it is proposed to monitor requests for more than 3 ablations using a prior approval system.
A6.3 **Identification Rules for Devices:** How are device costs captured?	**Not applicable**
A6.4 **Identification Rules for Activity:** How are activity costs captured? (e.g., are there first and follow up outpatient appointments?)	**Already correctly captured by an existing specialised service line (NCBPS code within the PSS Tool** NCBPS13B – APC Adult Specialist Cardiac services: Cardiac Electrophysiology and ablation. If activity costs are already captured please specify whether this service needs a separate code. **No**
Section B - Service Impact *To be completed by the Lead Commissioner*	

B1 Service Organisation	
B1.1 Describe how the service is currently organised? (i.e. tertiary centres, networked provision etc.)	The service is currently provided by NHS England (specialised commissioning) within 34, geographically spread, specialist cardiac centres *(NCBPS13B)* *Source:* Prescribed Specialised Services (PSP) FY 19-20
B1.2 Will the proposition change the way the commissioned service is organised?	**No** *Source: Prescribed Specialised Services (PSP) FY 19-20*
B2 Geography & Access	
B2.1 How is the service currently accessed (e.g., self-referral, referral from GP, secondary care, other)	In line with Service Specification A09/S/b Cardiology: Electrophysiology and Ablation Services Adult. Consultant to Consultant referral from secondary care. 99% of procedures are performed on an elective pathway, 1% non-elective (n=9000)

B2.2 What impact will the new policy have on the sources of referral?	**Unknown** Referrals will continue, from source, at the current rate, but the additional exclusion criteria will apply. For individual patients, this may mean that the treatment is not carried out where previously it was. This may see a reduction in referrals, but the number is uncertain.
B2.3 Is the new policy likely to improve equity[1] of access?	**Increase** Please specify: There is a wide variation in the rates of repeat procedures which this policy will cover. Unnecessary procedures or performing procedures with no evidence base will be reduced thereby releasing capacity for other patients. It is therefore expected that equity will be improved. *Source: Equalities Impact Assessment*
B2.4 Is the new policy likely to improve equality[1] of access and/or outcomes?	**Increase** Please specify: As this is predominantly an elective procedure, total procedures performed is most likely limited by service capacity. If the exclusion criteria reduce the number of procedures performed per patient, comparatively, this capacity could see a reduction in waiting lists, or additional capacity to support the anticipated annual growth of 5% annually. Ablation for AF is the only type of ablation where year on year growth is being experienced. *Source: Equalities Impact Assessment*

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

B3 Commissioning Responsibility

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)	**No change - NHSE** Please specify: The service will continue to be delivered via specialised commissioning designated cardiac centres.

Section C - Finance Impact

To be completed by the Finance Lead with the exception of C1.2

C1 Tariff/Pricing

C1.1 How is the service contracted and/or charged?

Only specify for the relevant

Select all that apply:

Drugs	Not separately charged – part of local or national tariffs	☐
	Excluded from tariff – pass through	☐
	Excluded from tariff – other	☐
Devices	Not separately charged – part of local or national tariffs	☐

<table>
<tr><td>section of the patient pathway</td><td>
<table>
<tr><td></td><td>Excluded from tariff (excluding HCTED programme) – pass through</td><td>☒</td></tr>
<tr><td></td><td>Excluded from tariff (excluding HCTED) – other</td><td>☐</td></tr>
<tr><td></td><td>Via HCTED model</td><td>☐</td></tr>
<tr><td rowspan="8">Activity</td><td>Paid entirely by National Tariffs</td><td>☐</td></tr>
<tr><td>Paid entirely by Local Tariffs</td><td>☐</td></tr>
<tr><td>Partially paid by National Tariffs</td><td>☒</td></tr>
<tr><td>Partially paid by Local Tariffs</td><td>☐</td></tr>
<tr><td>Part/fully paid under a Block arrangement</td><td>☐</td></tr>
<tr><td>Part/fully paid under Pass-Through arrangements</td><td>☐</td></tr>
<tr><td>Part/fully paid under Other arrangements</td><td>☐</td></tr>
</table>
</td></tr>
<tr><td>C1.2 Drug Costs (to be completed by the Clinical Policy Team)
Where not included in national or local tariffs, list each drug or combination, dosage, quantity, list price including VAT if applicable and</td><td>Not Applicable</td></tr>
</table>

<table>
<tr>
<td>any other key information e.g. Chemotherapy Regime, homecare costs. Provide a basis for this assumption.
NB discounted prices or local prices must not be included as these are subject to commercial confidentiality and must not be disclosed.</td>
<td></td>
</tr>
<tr>
<td>C1.3 Device Costs (to be completed by LC)
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</td>
<td>HCTED process covers both the three-dimensional mapping system, and also the ablation catheters.
£
Average Device Cost per patient 3,325
<table>
<tr><th>DEV Code</th><th>DEV Category</th></tr>
<tr><td>DEV01</td><td>3D Mapping and Linear Ablation Catheters</td></tr>
<tr><td>DEV18</td><td>RF Cryotherapy and Microwave Ablation Probes and Catheters</td></tr>
</table>
</td>
</tr>
</table>

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.	
C1.4 **Activity Costs covered by National Tariffs** *(to be completed by Finance)* 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.	Because ablation for cardiac dysrhythmia is carried out for a number of conditions it is the professional judgement of the PWG the procedure codes and subsequent costs in this assessment cover the patient cohort in this policy. K621 Percutaneous transluminal ablation of pulmonary vein to left atrial conducting system K575 Percutaneous transluminal ablation of atrial wall NEC.

C1.5 **Activity Costs covered by Local Tariff** *(to be completed by Finance)* 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.	Not Applicable
C1.6 **Other Activity Costs not covered by National or Local Tariff** *(to*	Not Applicable

be completed by Finance) Include descriptions and estimates of all key costs.	
C1.7 Are there any prior approval/notification mechanisms required either during implementation or permanently?	**Yes** The proposal includes developing a prior approval system for occasions when 3 ablations on individual patients have already been carried out.
C2 Average Cost per Patient	
C2.1 What is the average cost per patient per year for 5 years, including follow-up where required?	Include the cost per patient over 5 years e.g. 1 average patient starting on day 1 of year 1 continuing for 5 years (for ongoing treatment) or in any 1 financial year (for one-off treatments). Costs are **prior** to commercially confidential or volume-based discounts. Provide clear description of how the calculation was reached or provide the calculation. Source SUS Assumes annual calculated growth in demand of 4% annually if unchecked.

Revised Activity Figures on 19/20 Forecast baseline

(based on 4% annual growth)

Year	Total Activity Spells	Activity Change	Total Cost of Spells	Cost Change for Spells	% change		Cost of HCTED Devices	Cost Change for HCTED Devices	TOTAL COST CHANGE
Year 0	7,753		£ 34,635,561				£ 25,781,275		
Year 1	8,063	310	£ 36,020,984	£1,385,422	4.0%		£ 26,812,526	£ 1,031,251	£ 2,416,673
Year 2	8,386	323	£ 37,461,823	£1,440,839	4.0%		£ 27,885,027	£ 1,072,501	£ 2,513,340
Year 3	8,721	335	£ 38,960,296	£1,498,473	4.0%		£ 29,000,428	£ 1,115,401	£ 2,613,874
Year 4	9,070	349	£ 40,518,708	£1,558,412	4.0%		£ 30,160,445	£ 1,160,017	£ 2,718,429
Year 5	9,433	363	£ 42,139,456	£1,620,748	4.0%		£ 31,366,863	£ 1,206,418	£ 2,827,166

Average Cost per Spell	£	4,467
Average Cost of HCTED Devices	£	3,325

C3 Overall Cost Impact of this Policy to NHS England

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.

Source SUS data .

Year	TOTAL COST CHANGE
Year 0	
Year 1	£ 2,416,673.45
Year 2	£ 2,513,340.39

Total Annual Cost Change following Policy	cost reduction in >3 repeat procedures
£ 2,216,313.87	£ 311,694.77
£ 2,304,966.42	£ 324,162.56

cost reduction in >2 repeat procedures
£ 200,359.59
£ 208,373.97

Commercial in confidence discounts are not included therefore the actual cost pressure may be lower than stated.	Year 3	£ 2,613,874.01	£ 2,397,165.08	£ 337,129.06	£ 216,708.93	
	Year 4	£ 2,718,428.97	£ 2,493,051.68	£ 350,614.23	£ 225,377.28	
	Year 5	£ 2,827,166.12	£ 2,592,773.75	£ 364,638.80	£ 234,392.38	
C3.2 If the budget impact on NHS England cannot be identified set out the reasons why this cannot be measured.	NA					
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?	Not Required					

C4 Overall cost impact of this policy to the NHS as a whole

C4.1 Specify the budget impact of the proposal on other parts of the NHS.

Budget impact for CCGs:

No impact on CCGs

Budget impact for providers:

No impact on providers

C4.2 Taking into account responses to C3.1 and C4.1, specify the budget impact to the NHS as a whole.

Cost saving *(assuming growth predictions are correct)*

Source SUS data .

Year	TOTAL COST CHANGE	Total Annual Cost Change following Policy	cost reduction in >3 repeat procedures	cost reduction in >2 repeat procedures
Year 0				
Year 1	£ 2,416,673.45	£ 2,216,313.87	£ 311,694.77	£ 200,359.59
Year 2	£ 2,513,340.39	£ 2,304,966.42	£ 324,162.56	£ 208,373.97
Year 3	£ 2,613,874.01	£ 2,397,165.08	£ 337,129.06	£ 216,708.93
Year 4	£ 2,718,428.97	£ 2,493,051.68	£ 350,614.23	£ 225,377.28
Year 5	£ 2,827,166.12	£ 2,592,773.75	£ 364,638.80	£ 234,392.38

C4.3 Are there likely to be any

No

Please specify:

costs or savings for non-NHS commissioners and/or public sector funders?	All costs are within tariff.
C5 Funding	
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.	The costs provided represent anticipated growth in number of procedures based upon rates of left atrial ablation and the impact of the policy on growth predictions less the impact of the policy on repeat rates.
C6 Financial Risks Associated with Implementing this Policy	
C6.1 Describe the parameters	The risk profile of the policy would be to assume that the policy has no impact, in which case annual growth would continue at approximately 4% per annum. The likely impact of the policy is that

used to generate the low, mid and high case scenarios for patient numbers and activity. Specify the range.	procedures will be reduce by approximately 290 procedures per year yielding a reduction on annual costs of approximately 360K per year
C6.2 What scenario has been recommended and why? What would be the impact of a discounted scenario?	NA
C7 Cost Profile	
C7.1 Factors which impact on costs	**Yes** If yes, specify type and range: Number of repeat procedures for Lt atrial ablation

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)

<table>
<tr><td></td><td></td><td>Source</td><td>Please specify any further detail</td></tr>
<tr><td>Number of patients who meet the proposed commissioning criteria and who would be treated if the proposal is approved per year.</td><td>7753 patient procedures in year 0 and increasing by 4% per annum thereafter. Some patients may receive more than one procedure in separate spells of care.</td><td>SUS data</td><td>The figure represents the total number of Lt Atrial ablation procedures performed in FY 18-19 as a subset set of total cardiac ablations. This was a professionally led decision as to what constitutes ablation for AF alone.</td></tr>
<tr><td>Age group for which the treatment is proposed according to the proposed criteria</td><td>Policy is for all adults aged 18 years and over.</td><td>Professional decision by PWG. Children may suffer from abnormally fast heart rates but not due to AF.</td><td></td></tr>
<tr><td>Age distribution of the patient population eligible according to the proposed criteria</td><td>Policy is for all adults aged 18 years and over.</td><td>Professional decision by PWG. Children may suffer from abnormally fast heart rates but not due to AF.</td><td></td></tr>
<tr><td>How is the population currently geographically distributed</td><td>Unevenly
<table><tr><th>FY 2018/19</th><th>Number</th><th>%</th></tr><tr><td>North West</td><td>1090</td><td>15</td></tr><tr><td>North East and Yorkshire</td><td>944</td><td>13</td></tr><tr><td>Midlands</td><td>977</td><td>13</td></tr><tr><td>East of England</td><td>531</td><td>7</td></tr><tr><td>London</td><td>2536</td><td>35</td></tr></table></td><td>Policy proposition (section 6)</td><td></td></tr>
</table>

	<table><tr><td>South East</td><td>761</td><td>10</td></tr><tr><td>South West</td><td>486</td><td>7</td></tr><tr><td>Totals</td><td>7325</td><td>100</td></tr></table> *Based on NCDR data, used to demonstrate regional variation, hence further need for the policy*		
What are the growth assumptions for the disease / condition?	*The assumption is that the number of eligible patients will grow by 4% per year. There may be a small reduction in repeat procedures because of the exclusion criteria. This may partially offset the annual increase.*	*Policy proposition (section 6)*	
Is there evidence of current inequalities in access to service or outcomes?	*There is some evidence (NICOR 16-17) that some providers may have a repeat procedure rate out of range. This policy aims to give guidance on how many procedures should be performed.*		
Is there evidence that implementing the policy/service specification will improve current inequities of access or outcomes?	*Yes, a minimal amount of capacity may be released by restricting the number of procedures per patient. This may not be enough to cover anticipated annual growth.*		