

## Integrated Impact Assessment Report for Clinical Commissioning Policies

<b>Policy Reference Number</b>	1692		
<b>Policy Title</b>	Left Atrial Appendage Occlusion (LAAO) for patients with atrial fibrillation and relative or absolute contraindications to anticoagulation (adults) Proposal <b><u>for routine commission</u></b> (ref A3.1)		
<b>Lead Commissioner</b>	Andy Hughes	<b>Clinical Lead</b>	David Hildick-Smith
<b>Finance Lead</b>	Craig Charlton	<b>Analytical Lead</b>	Craig Charlton

### Integrated Impact Assessment – Index

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About this Impact Assessment: instructions for completion and explanatory notes
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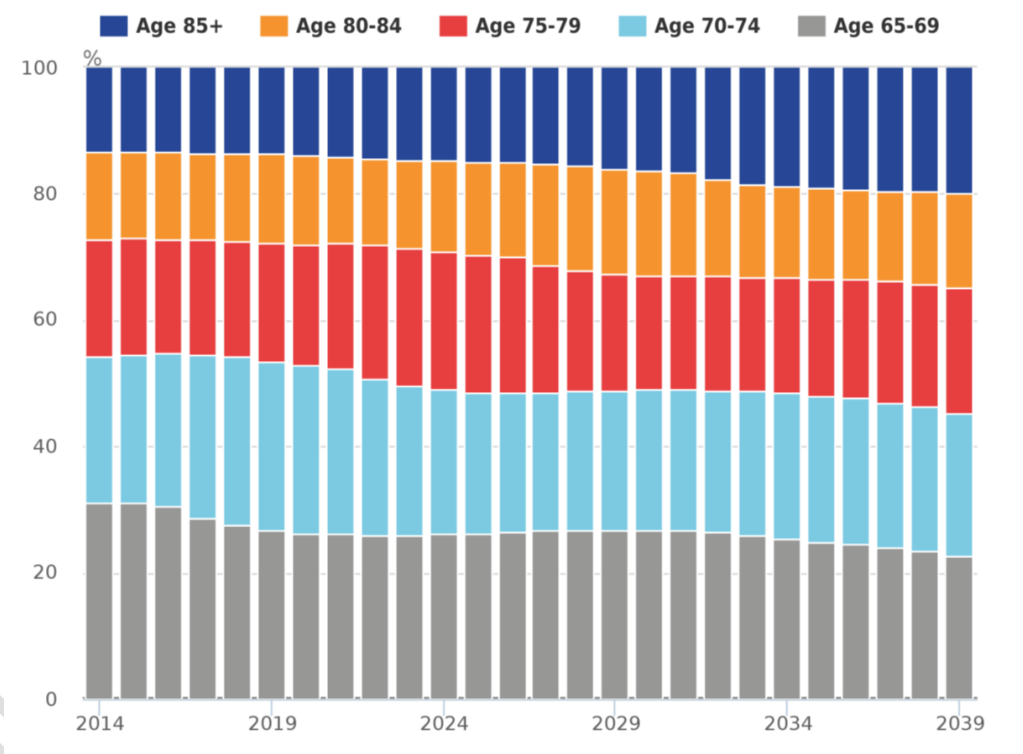
- Each section is divided into themes.
- Each theme sets out a number of questions.
- All questions are answered by selecting a drop down option or including free text.
- Free text boxes are provided to enable succinct relevant commentary to be added which explains the rationale for response or assumption. 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.

## Section A - Activity Impact

### A1 Current Patient Population & Demography / Growth

A1.1 Prevalence of the disease/condition.	<p>In a population of 53 million (England) there are 800,000 diagnosed with AF of which 650,000 have a risk profile requiring treatment and up to 30,000 may have relative contraindications to oral anticoagulants (OAC). Of these 30,000, half will be given anticoagulants anyway because the associated risks are felt to be low. Of the remaining 15,000 many will be frail and elderly, with a short life expectancy, or with comorbidities that make LAAO unsuitable. Of the remaining 5000 patients, about half are likely to be managed in general practice. Of the 2500 patients in secondary care, many will not be referred for LAAO, many will not want to be considered for LAAO, and some will be put off by the need for a general anaesthetic and the risks of the procedure. As a result the annual population for LAAO is expected to rise from 400 to a steady state of 1000 after 5 years.</p> <p><i>Source: Policy Proposition section 6</i></p>
A1.2 Number of patients currently eligible for the treatment according to the proposed policy commissioning criteria.	<p>400 in year 1 rising to 1000 in year 5</p> <p><i>Source: Epidemiology and clinical experience of the procedure PRIOR to and during Commissioning through Evaluation (CtE) from two high volume early adopting centres.</i></p>
A1.3 Age group for which the treatment is proposed according to the policy commissioning criteria.	<p><b><u>Adults</u></b></p> <p>Please specify</p> <p>18 years and over</p>
A1.4 Age distribution of the patient population eligible according to the proposed policy commissioning criteria	<p>18 and above relevant but mainly those of advanced age eg 65-80+ years</p> <p><i>Source: American Heart Association</i></p>

	<p>Please specify</p> <p>Atrial Fibrillation is very rare in children. AF is associated with a 5 times increased risk of stroke which tends to be ischaemic and more severe.</p>								
A1.5 How is the population currently distributed geographically?	<p><b><u>Evenly</u></b></p> <p>If unevenly, estimate regional distribution by %:</p> <table border="1"> <tr> <td>North</td><td></td></tr> <tr> <td>Midlands &amp; East</td><td></td></tr> <tr> <td>London</td><td></td></tr> <tr> <td>South</td><td></td></tr> </table> <p><i>Source: The 2016 Office of National Statistics (ONS) population figures continue to show that there continues to be an increase in the aging population:</i></p> <p>Please specify</p> <p>The population of England is projected to grow by 4.1 million (7.5%) by mid-2024. The projected growth varies considerably by different age groups. The fastest-growing age group (people aged 65 and over) is projected to grow by 20.4% over 10 years and by nearly 60% over 25 years in England. This age group is projected to increase both in absolute and proportionate terms. This means that not only is this population group projected to continue to grow, but also the share of this age group of the total population is projected to get larger.</p>	North		Midlands & East		London		South	
North									
Midlands & East									
London									
South									



## A2 Future Patient Population & Demography

A2.1 Projected changes in the disease/condition epidemiology, such as incidence or prevalence (prior to applying the new policy) in 2, 5, and 10 years?

### Increasing

The estimated prevalence of Atrial Fibrillation (AF) in the general population is 1-2% and increases with age. The prevalence of AF doubles with each advancing decade of age from 0.5% at age 50-59 years to almost 9% at age 80-89 years. Stroke is a major health problem in the UK. Each year, approximately 110,000 people in England have a first or recurrent stroke. Most people survive a first stroke but often have significant morbidity. More than 900,000 people in England

	<p>are living with the effects of stroke.</p> <p>Hence the prevention of AF related stroke remains clinically and economically important.</p> <p><i>Source: The 2016 ONS population figures continue to show that there continues to be an increase in the aging population.</i></p>											
A2.2 Are there likely to be changes in demography of the patient population and would this impact on activity/outcomes?	<p><b><u>Yes</u></b></p> <p>Please specify</p> <p>See A1.5.</p>											
A2.3 Expected net increase or decrease in the number of patients who will be eligible for the service, according to the proposed service specification commissioning criteria, per year in years 2-5 and 10?	<table><tr><td>YR2 +/-</td><td>101</td></tr><tr><td>YR3 +/-</td><td>151</td></tr><tr><td>YR4 +/-</td><td>150</td></tr><tr><td>YR5 +/-</td><td>202</td></tr><tr><td>YR10 +/-</td><td>7</td></tr></table>	YR2 +/-	101	YR3 +/-	151	YR4 +/-	150	YR5 +/-	202	YR10 +/-	7	
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YR3 +/-	151											
YR4 +/-	150											
YR5 +/-	202											
YR10 +/-	7											
Are these numbers in line with ONS growth assumptions for the age specific population? If not please justify the growth assumptions made.	<p><b><u>Yes</u></b></p> <p>The increase in activity in years 1 to 5 is due to the gradual building of capacity to deliver the service and increasing awareness and education of health professionals in primary and secondary care of access to the service, eligibility criteria and clinical benefits in stroke prevention. From year 5 onwards growth is in line with ONS assumptions.</p>											

A3 Activity													
A3.1 What is the purpose of new policy?	<p><b><u>Revise existing policy (expand or restrict an existing treatment threshold)</u></b></p> <p>Please specify            NHSCB/A09/PS/c Left Atrial Appendage (LAA) Occlusion            Dated April 2013. The aim is to reduce the risk of ischaemic stroke in patients at high risk of stroke, but who are unsuitable/contraindicated for currently available prophylaxis with oral anticoagulant drugs.</p>												
A3.2 What is the annual activity associated with the existing pathway for the eligible population?	<p>none</p> <p>Please specify            Procedure is not routinely commissioned</p>												
A3.3 What is the estimated annual activity associated with the proposed policy proposition pathway for the eligible population?	<p>It is estimated that each patient will require the activity in the table below with the number of patients being 400 in year 1 rising to 1000 in year 5</p> <table border="1"> <thead> <tr> <th>Activity</th> <th>Count</th> </tr> </thead> <tbody> <tr> <td>Outpatient First attendance - Single professional</td> <td>1</td> </tr> <tr> <td>Outpatient Follow up - Single Professional</td> <td>2</td> </tr> <tr> <td>Device Costs</td> <td>1</td> </tr> <tr> <td>Procedure tariff</td> <td>1</td> </tr> <tr> <td>ECG costs</td> <td>1</td> </tr> </tbody> </table>	Activity	Count	Outpatient First attendance - Single professional	1	Outpatient Follow up - Single Professional	2	Device Costs	1	Procedure tariff	1	ECG costs	1
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A3.4 What is the estimated annual activity associated with the next best alternative comparator pathway for the eligible population? If the only alternative is the existing pathway, please state 'not applicable' and move to A4.	Not applicable												
A4 Existing Patient Pathway													

<p><b>A4.1 Existing pathway:</b> Describe the relevant currently routinely commissioned:</p> <ul style="list-style-type: none"> <li>• Treatment or intervention</li> <li>• Patient pathway</li> <li>• Eligibility and/or uptake estimates.</li> </ul>	<p>OAC therapy options would likely be unsuitable/ contraindicated for patients with a prior history of / at high risk of major haemorrhage e.g. intracranial or gastroenterological haemorrhage. A history of spontaneous or OAC associated ICH increases the risk of recurrent haemorrhage with potentially devastating clinical consequences. Consequently, these patients are unprotected from the risk of stroke. Current standard of care is that patients who meet NICE Guidance CG180 criteria of a CHA2DS2-VASc score of 2 or above, will be offered oral anticoagulant treatment taking bleeding risk into account.</p>
<p><b>A4.2.</b> What are the current treatment access and stopping criteria?</p>	<p>Not applicable</p>
<p><b>A4.3</b> What percentage of the total eligible population is expected to:</p> <ol style="list-style-type: none"> <li>Be clinically assessed for treatment</li> <li>Be considered to meet an exclusion criteria following assessment</li> <li>Choose to initiate treatment</li> <li>Comply with treatment</li> <li>Complete treatment?</li> </ol>	<p>Not applicable</p>
<p><b>A5 Comparator (next best alternative treatment) Patient Pathway</b> (NB: comparator/next best alternative does not refer to current pathway but to an alternative option)</p>	
<p><b>A5.1 Next best comparator:</b> Is there another 'next best' alternative treatment which is a relevant comparator?</p>	<p><b><u>No</u></b></p>



<p><i>If yes, describe relevant</i></p> <ul style="list-style-type: none"> <li>• <i>Treatment or intervention</i></li> <li>• <i>Patient pathway</i></li> <li>• <i>Actual or estimated eligibility and uptake</i></li> </ul>	
<p>A5.2 What percentage of the total eligible population is estimated to:</p> <ul style="list-style-type: none"> <li>a) Be clinically assessed for treatment</li> <li>b) Be considered to meet an exclusion criteria following assessment</li> <li>c) Choose to initiate treatment</li> <li>d) Comply with treatment</li> <li>e) Complete treatment?</li> </ul>	Not applicable
<p><b>A6 New Patient Pathway</b></p>	
<p>A6.1 What percentage of the total eligible population is expected to:</p> <ul style="list-style-type: none"> <li>a) Be clinically assessed for treatment</li> <li>b) Be considered to meet an exclusion criteria following assessment</li> <li>c) Choose to initiate treatment</li> <li>d) Comply with treatment</li> <li>e) Complete treatment?</li> </ul>	<p>If not known, please specify</p> <ul style="list-style-type: none"> <li>a) 30</li> <li>b) 15</li> <li>c) 8</li> <li>d) 8</li> <li>e) 8</li> </ul>
<p>A6.2 Specify the nature and duration of the proposed new treatment or intervention.</p>	<p><b><u>Time limited</u></b></p> <p>For time limited treatments, specify frequency and/or duration.</p> <p>The procedure is usually carried out under general anaesthetic with the use of</p>

	<p>echocardiographic and fluoroscopy guidance. It requires placement of a catheter in the right femoral vein, followed by puncture of the inter-atrial septum of the heart. The LAA can then be accessed and a device is then inserted and expanded to fill the site and close off the appendage. The duration of the procedure is approximately one hour. Patients will normally have 1 follow up appointment and will be assessed for single or dual antiplatelet therapy for a minimum of six months following implant</p>																			
<b>A7 Treatment Setting</b>																				
A7.1 How is this treatment delivered to the patient?	<p><i>Select all that apply:</i></p> <table border="1"> <tr> <td>Emergency/Urgent care attendance</td><td><input type="checkbox"/></td></tr> <tr> <td>Acute Trust: inpatient</td><td><input checked="" type="checkbox"/></td></tr> <tr> <td>Acute Trust: day patient</td><td><input checked="" type="checkbox"/></td></tr> <tr> <td>Acute Trust: outpatient</td><td><input checked="" type="checkbox"/></td></tr> <tr> <td>Mental Health provider: inpatient</td><td><input type="checkbox"/></td></tr> <tr> <td>Mental Health provider: outpatient</td><td><input type="checkbox"/></td></tr> <tr> <td>Community setting</td><td><input type="checkbox"/></td></tr> <tr> <td>Homecare</td><td><input type="checkbox"/></td></tr> <tr> <td>Other</td><td><input type="checkbox"/></td></tr> </table>		Emergency/Urgent care attendance	<input type="checkbox"/>	Acute Trust: inpatient	<input checked="" type="checkbox"/>	Acute Trust: day patient	<input checked="" type="checkbox"/>	Acute Trust: outpatient	<input checked="" type="checkbox"/>	Mental Health provider: inpatient	<input type="checkbox"/>	Mental Health provider: outpatient	<input type="checkbox"/>	Community setting	<input type="checkbox"/>	Homecare	<input type="checkbox"/>	Other	<input type="checkbox"/>
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Homecare	<input type="checkbox"/>																			
Other	<input type="checkbox"/>																			
A7.2 What is the current number of contracted providers for the eligible population by region?	<table border="1"> <tr> <td>NORTH</td><td>0</td></tr> </table>		NORTH	0																
NORTH	0																			

	<table border="1"> <tr> <td>MIDLANDS &amp; EAST</td> <td>0</td> </tr> <tr> <td>LONDON</td> <td>0</td> </tr> <tr> <td>SOUTH</td> <td>0</td> </tr> </table>	MIDLANDS & EAST	0	LONDON	0	SOUTH	0	<p>The are no commissioned providers of the service</p>												
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<p>A7.3 Does the proposition require a change of delivery setting or capacity requirements?</p>	<p><b>yes</b>  Please specify:  A procurement will be required to commission specialised tertiary cardiac centres to deliver the service</p>																			
<p><b>A8 Coding</b></p>																				
<p>A8.1 Specify the datasets used to record the new patient pathway activity.</p> <p>*expected to be populated for all commissioned activity</p>	<p><i>Select all that apply:</i></p> <table border="1"> <tr> <td>Aggregate Contract Monitoring *</td> <td><input checked="" type="checkbox"/></td> </tr> <tr> <td>Patient level contract monitoring</td> <td><input checked="" type="checkbox"/></td> </tr> <tr> <td>Patient level drugs dataset</td> <td><input type="checkbox"/></td> </tr> <tr> <td>Patient level devices dataset</td> <td><input checked="" type="checkbox"/></td> </tr> <tr> <td>Devices supply chain reconciliation dataset</td> <td><input checked="" type="checkbox"/></td> </tr> <tr> <td>Secondary Usage Service (SUS+)</td> <td><input checked="" type="checkbox"/></td> </tr> <tr> <td>Mental Health Services DataSet (MHSDS)</td> <td><input type="checkbox"/></td> </tr> <tr> <td>National Return**</td> <td><input type="checkbox"/></td> </tr> <tr> <td>Clinical Database**</td> <td><input checked="" type="checkbox"/></td> </tr> </table>		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 checked="" type="checkbox"/>	Devices supply chain reconciliation dataset	<input checked="" 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 checked="" type="checkbox"/>
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	<table border="1"> <tr> <td data-bbox="985 97 1653 156">Other**</td><td data-bbox="1653 97 1749 156"><input type="checkbox"/></td></tr> </table> <p>**If National Return, Clinical database or other selected, please specify: Funding of £100k per year for the first 3 years for a National Registry have been included in the Impact Assessment. It is expected that the costs will be incorporated into reference costs and thus incorporated into tariff from year 4 onwards</p>	Other**	<input type="checkbox"/>												
Other**	<input type="checkbox"/>														
<p>A8.2 Specify how the activity related to the new patient pathway will be identified.</p>	<p><i>Select all that apply:</i></p> <table border="1"> <tr> <td data-bbox="985 416 1653 475">OPCS v4.8</td><td data-bbox="1653 416 1749 475"><input checked="" type="checkbox"/></td></tr> <tr> <td data-bbox="985 475 1653 534">ICD10</td><td data-bbox="1653 475 1749 534"><input checked="" type="checkbox"/></td></tr> <tr> <td data-bbox="985 534 1653 593">Treatment function code</td><td data-bbox="1653 534 1749 593"><input checked="" type="checkbox"/></td></tr> <tr> <td data-bbox="985 593 1653 652">Main Speciality code</td><td data-bbox="1653 593 1749 652"><input type="checkbox"/></td></tr> <tr> <td data-bbox="985 652 1653 711">HRG</td><td data-bbox="1653 652 1749 711"><input checked="" type="checkbox"/></td></tr> <tr> <td data-bbox="985 711 1653 770">SNOMED</td><td data-bbox="1653 711 1749 770"><input type="checkbox"/></td></tr> <tr> <td data-bbox="985 770 1653 863">Clinical coding / terming methodology used by clinical profession</td><td data-bbox="1653 770 1749 863"><input type="checkbox"/></td></tr> </table>	OPCS v4.8	<input checked="" type="checkbox"/>	ICD10	<input checked="" type="checkbox"/>	Treatment function code	<input checked="" type="checkbox"/>	Main Speciality code	<input type="checkbox"/>	HRG	<input checked="" type="checkbox"/>	SNOMED	<input type="checkbox"/>	Clinical coding / terming methodology used by clinical profession	<input type="checkbox"/>
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<p><b>A8.3 Identification Rules for Drugs:</b> How are drug costs captured?</p>	<p><b><u>Not applicable</u></b></p> <p>If the drug has already been specified in the current NHS England Drug List please specify drug name and drug indication:</p> <p>If the drug has NOT already been specified in the current NHS England Drug List please give details of action required and confirm that this has been discussed with the pharmacy lead:</p>														
<p><b>A8.4 Identification Rules for Devices:</b> How are device costs captured?</p>	<p><b><u>Already covered by an existing category of HCTED but not commissioned via the Zero Cost Model</u></b></p>														

	<p>If the device is covered by an existing category of HCTED please specify the Device Category (as per the National Tariff Payment System Guidance).</p> <p>Occluder Vascular Appendage and septal devices</p> <p>If the device is not excluded from Tariff <b>nor</b> covered within existing National or Local prices please specify details of action required and confirm that this has been discussed with the HCTED team.</p>
How are activity costs captured?	<p><b><u>Not captured by an existing specialised service line</u></b></p> <p>If activity costs are already captured please specify the specialised service code and description (e.g. NCBPS01C Chemotherapy).</p> <p>If activity costs are already captured please specify whether this service needs a separate code. <b><u>No</u></b></p> <p>K62.5 Percutaneous transluminal occlusion of left atrial appendage is not currently being captured in the Service Line Code NCBPS13B Cardiology: Cardiac Electrophysiology And Ablation Services</p> <p>If the activity is captured but the service line needs amendment please specify whether the proposed amendments have been documented and agreed with the Identification Rules team.</p> <p>No</p> <p>If the activity is not captured please specify whether the proposed identification rules have been documented and agreed with the Identification Rules team. <b><u>No</u></b></p>
<b>A9 Monitoring</b>	
<b>A9.1 Contracts</b> Specify any new or revised data flow or data collection	<b><u>None</u></b>

requirements, needed for inclusion in the NHS Standard Contract Information Schedule.							
<b>A9.2 Excluded Drugs and Devices (not covered by the Zero Cost Model)</b> For treatments which are tariff excluded drugs or devices not covered by the Zero Cost Model, specify the pharmacy or device monitoring required, for example reporting or use of prior approval systems.	Select all that apply: <table border="1"> <tr> <td>Drugs or Device MDS</td> <td><input checked="" type="checkbox"/></td> </tr> <tr> <td>Blueteq</td> <td><input checked="" type="checkbox"/></td> </tr> <tr> <td>Other prior approval</td> <td><input type="checkbox"/></td> </tr> </table>	Drugs or Device MDS	<input checked="" type="checkbox"/>	Blueteq	<input checked="" type="checkbox"/>	Other prior approval	<input type="checkbox"/>
Drugs or Device MDS	<input checked="" type="checkbox"/>						
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Other prior approval	<input type="checkbox"/>						
<b>A9.3 Business intelligence</b> Is there potential for duplicate reporting?	<b><u>No</u></b>						
<b>A9.4 Contract monitoring</b> Is this part of routine contract monitoring?	<b><u>Yes</u></b> If yes, please specify contract monitoring requirement: Activity will be reported in line with Schedule 6 of the NHS Standard Contract						
<b>A9.5 Dashboard reporting</b> Specify whether a dashboard exists for the proposed intervention?	<b><u>No</u></b> If yes, specify how routine performance monitoring data will be used for dashboard reporting. If no, will one be developed? This will be added to the cardiac dashboard						
<b>A9.6 NICE reporting</b> Are there any directly applicable NICE or equivalent quality standards which need to be monitored in association with the new policy?	<b><u>No</u></b>						
<b>Section B - Service Impact</b>							

B1 Service Organisation									
B1.1 Describe how the service is currently organised? (i.e. tertiary centres, networked provision etc.)	The service is not routinely commissioned <i>Source:</i> Clinical Commissioning Policy Statement: Left Atrial Appendage Occlusion (LAAO) April 2013 Reference: NHSCB/A09/PS/c								
B1.2 Will the proposition change the way the commissioned service is organised?	<b><u>Yes</u></b> Please specify: Providers will be selected to provide the service when commissioned.								
B1.3 Will the proposition require a new approach to the organisation of care?	<b><u>No change to delivery of care</u></b> Please specify: Service delivery will be subsumed into the current specialised cardiac interventional services								
B2 Geography & Access									
B2.1 Where do current referrals come from?	<i>Select all that apply:</i> <table border="1"> <tbody> <tr> <td>GP</td> <td><input type="checkbox"/></td> </tr> <tr> <td>Secondary care</td> <td><input checked="" type="checkbox"/></td> </tr> <tr> <td>Tertiary care</td> <td><input checked="" type="checkbox"/></td> </tr> <tr> <td>Other</td> <td><input type="checkbox"/></td> </tr> </tbody> </table>	GP	<input type="checkbox"/>	Secondary care	<input checked="" type="checkbox"/>	Tertiary care	<input checked="" type="checkbox"/>	Other	<input type="checkbox"/>
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Secondary care	<input checked="" type="checkbox"/>								
Tertiary care	<input checked="" type="checkbox"/>								
Other	<input type="checkbox"/>								
B2.2 What impact will the new policy have on the sources of	<b><u>No impact</u></b>								

referral?	
B2.3 Is the new policy likely to improve equity of access?	<p><b><u>No impact</u></b></p> <p><i>Source: Equalities Impact Assessment</i></p>
B2.4 Is the new policy likely to improve equality of access and/or outcomes?	<p><b><u>No impact</u></b></p> <p>Please specify:</p> <p>The new policy is likely to provide stroke prevention to patients who are at high risk of stroke but cannot for clinical contraindication reasons benefit from oral anticoagulant therapy.</p> <p><i>Source: NHSCB/A09/PS/c Left Atrial Appendage (LAA) Occlusion</i></p> <p><i>Dated April 2013</i></p>
<b>B3 Implementation</b>	
B3.1 Will commissioning or provider action be required before implementation of the proposition can occur?	<p><b><u>Procurement action</u></b></p> <p>Please specify:</p> <p>There are currently no commissioned providers, procurement will be required to commission centres to deliver the intervention</p>
<p><b>B3.2 Time to implementation:</b></p> <p>Is a lead-in time required prior to implementation?</p>	<p><b><u>Yes - go to B3.3</u></b></p> <p>If yes, specify the likely time to implementation: 12 months</p>
<p><b>B3.3 Time to implementation:</b></p> <p>If lead-in time is required prior to implementation, will an interim plan for implementation be required?</p>	<p><b><u>Yes</u></b></p> <p>If yes, outline the plan:</p> <p>An interim plan may be required</p>



B3.4 Is a change in provider physical infrastructure required?	<b>No</b> Please specify: The procedure can be delivered within current specialised cardiac facilities												
B3.5 Is a change in provider staffing required?	<b>Yes</b> Please specify: There may be a requirement to increase staff to deliver the new procedure												
B3.6 Are there new clinical dependency and/or adjacency requirements that would need to be in place?	<b>No</b> Please specify: All the specialities within a tertiary cardiac and cardiothoracic centre and specialised cardiology support in line with current service specification for Cardiac Surgery - Adults												
B3.7 Are there changes in the support services that need to be in place?	<b>No</b>												
B3.8 Is there a change in provider and/or inter-provider governance required? (e.g. ODN arrangements / prime contractor)	<b>No</b> Please specify: Services are not currently commissioned												
B3.9 Is there likely to be either an increase or decrease in the number of commissioned providers? If yes, specify the current and estimated number of providers required in each region	<b>Increase</b> <i>Please complete table:</i> <table><tr><th>Region</th><th>Current no. of providers</th><th>Future State expected range</th><th>Provisional or confirmed</th></tr><tr><td>North</td><td>0</td><td>3</td><td><u>P</u></td></tr><tr><td>Midlands &amp;</td><td>0</td><td>2</td><td><u>P</u></td></tr></table>	Region	Current no. of providers	Future State expected range	Provisional or confirmed	North	0	3	<u>P</u>	Midlands &	0	2	<u>P</u>
Region	Current no. of providers	Future State expected range	Provisional or confirmed										
North	0	3	<u>P</u>										
Midlands &	0	2	<u>P</u>										

	East			
	London	0	3	<u>P</u>
	South	0	2	<u>P</u>
	Total	0	10	<u>P</u>

Please specify:  
The intervention is not routinely commissioned but future locations are likely to be selected from current specialised tertiary cardiac centres who have experience of both providing the procedure and the service.

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B3.10 Specify how revised provision will be secured by NHS England as the responsible commissioner.

*Select all that apply:*

Publication and notification of new policy	<input checked="" type="checkbox"/>
Market intervention required	<input checked="" type="checkbox"/>
Competitive selection process to secure increase or decrease provider configuration	<input type="checkbox"/>
Price-based selection process to maximise cost effectiveness	<input type="checkbox"/>
Any qualified provider	<input type="checkbox"/>
National Commercial Agreements e.g. drugs, devices	<input type="checkbox"/>
Procurement	<input type="checkbox"/>
Other	<input type="checkbox"/>

Please specify:  
Future provision will be secured through procurement

---

**B4 Place-based Commissioning**

B4.1 Is this service currently subject to, or planned for, place-based commissioning arrangements? (e.g. future CCG lead, devolved commissioning arrangements, STPs)	<b>No</b>																																	
<b>Section C - Finance Impact</b>																																		
<b>C1 Tariff/Pricing</b>																																		
C1.1 How is the service contracted and/or charged? Only specify for the relevant section of the patient pathway	<p><i>Select all that apply:</i></p> <table border="1"> <tr> <td data-bbox="976 502 1142 686" rowspan="3"><b>Drugs</b></td> <td data-bbox="1142 502 1960 566">Not separately charged – part of local or national tariffs</td> <td data-bbox="1960 502 2038 566"><input type="checkbox"/></td> </tr> <tr> <td data-bbox="1142 566 1960 630">Excluded from tariff – pass through</td> <td data-bbox="1960 566 2038 630"><input type="checkbox"/></td> </tr> <tr> <td data-bbox="1142 630 1960 686">Excluded from tariff - other</td> <td data-bbox="1960 630 2038 686"><input type="checkbox"/></td> </tr> <tr> <td data-bbox="976 686 1142 917" rowspan="4"><b>Devices</b></td> <td data-bbox="1142 686 1960 742">Not separately charged – part of local or national tariffs</td> <td data-bbox="1960 686 2038 742"><input type="checkbox"/></td> </tr> <tr> <td data-bbox="1142 742 1960 805">Excluded from tariff (excluding ZCM) – pass through</td> <td data-bbox="1960 742 2038 805"><input checked="" type="checkbox"/></td> </tr> <tr> <td data-bbox="1142 805 1960 869">Excluded from tariff (excluding ZCM) – other</td> <td data-bbox="1960 805 2038 869"><input type="checkbox"/></td> </tr> <tr> <td data-bbox="1142 869 1960 917">Via Zero Cost Model</td> <td data-bbox="1960 869 2038 917"><input type="checkbox"/></td> </tr> <tr> <td data-bbox="976 917 1142 1332" rowspan="7"><b>Activity</b></td> <td data-bbox="1142 917 1960 981">Paid entirely by National Tariffs</td> <td data-bbox="1960 917 2038 981"><input checked="" type="checkbox"/></td> </tr> <tr> <td data-bbox="1142 981 1960 1045">Paid entirely by Local Tariffs</td> <td data-bbox="1960 981 2038 1045"><input type="checkbox"/></td> </tr> <tr> <td data-bbox="1142 1045 1960 1109">Partially paid by National Tariffs</td> <td data-bbox="1960 1045 2038 1109"><input type="checkbox"/></td> </tr> <tr> <td data-bbox="1142 1109 1960 1173">Partially paid by Local Tariffs</td> <td data-bbox="1960 1109 2038 1173"><input type="checkbox"/></td> </tr> <tr> <td data-bbox="1142 1173 1960 1236">Part/fully paid under a Block arrangement</td> <td data-bbox="1960 1173 2038 1236"><input type="checkbox"/></td> </tr> <tr> <td data-bbox="1142 1236 1960 1300">Part/fully paid under Pass-Through arrangements</td> <td data-bbox="1960 1236 2038 1300"><input type="checkbox"/></td> </tr> <tr> <td data-bbox="1142 1300 1960 1332">Part/fully paid under Other arrangements</td> <td data-bbox="1960 1300 2038 1332"><input type="checkbox"/></td> </tr> </table>			<b>Drugs</b>	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"/>	<b>Devices</b>	Not separately charged – part of local or national tariffs	<input type="checkbox"/>	Excluded from tariff (excluding ZCM) – pass through	<input checked="" type="checkbox"/>	Excluded from tariff (excluding ZCM) – other	<input type="checkbox"/>	Via Zero Cost Model	<input type="checkbox"/>	<b>Activity</b>	Paid entirely by National Tariffs	<input checked="" type="checkbox"/>	Paid entirely by Local Tariffs	<input type="checkbox"/>	Partially paid by National Tariffs	<input 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 type="checkbox"/>	Part/fully paid under Other arrangements	<input type="checkbox"/>
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<p><b>C1.2 Drug Costs</b></p> <p>Where not included in national or local tariffs, list each drug or combination, dosage, quantity, <b>list</b> price including VAT if applicable and any other key information e.g. Chemotherapy Regime.</p> <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><b>C1.3 Device Costs</b></p> <p>Where not included in national or local tariff, list each element of the excluded device, quantity, <b>list or expected</b> price including VAT if applicable and any other key information.</p> <p>NB: Discounted prices or local prices must not be included as these are subject to commercial confidentiality and must not be disclosed.</p>	£4,000 per device												
<p><b>C1.4 Activity Costs covered by National Tariffs</b></p> <p>List all the HRG codes, HRG descriptions, national tariffs (excluding MFF), volume and other key costs (e.g. specialist top up %)</p>	<p>There is a cardiac surgery top up of 14.9%. A full list of applicable HRGs are included in the finance spreadsheet, an overview of the costs covered by tariff are in the table below:</p> <table border="1"> <thead> <tr> <th>Activity</th><th>Cost</th></tr> </thead> <tbody> <tr> <td>Outpatient First attendance - Single professional</td><td>262</td></tr> <tr> <td>Outpatient Follow up - Single Professional</td><td>131</td></tr> <tr> <td>Device Costs</td><td>4,000</td></tr> <tr> <td>Procedure tariff</td><td>7,296</td></tr> <tr> <td>ECG costs</td><td>178</td></tr> </tbody> </table>	Activity	Cost	Outpatient First attendance - Single professional	262	Outpatient Follow up - Single Professional	131	Device Costs	4,000	Procedure tariff	7,296	ECG costs	178
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<b>C1.5 Activity Costs covered by Local Tariff</b> 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 it has been derived, validated and tested.	Not applicable		
<b>C1.6 Other Activity Costs not covered by National or Local Tariff</b> Include descriptions and estimates of all key costs.	Not applicable		
<b>C1.7</b> Are there any prior approval mechanisms required either during implementation or permanently?	<b><u>No</u></b>		
<b>C2 Average Cost per Patient</b>			
<b>C2.1</b> What is the estimated cost per patient to NHS England, in years 1-5, including follow-up where required?      Are there any changes expected in year 6-10 which would impact the model?	YR1	£6,343	
	YR2	£6,313	
	YR3	£6,286	
	YR4	£6,269	
	YR5	£6,254	
	No		
<b>C3 Overall Cost Impact of this Policy to NHS England</b>			

<p>C3.1 Specify the budget impact of the proposal on NHS England in relation to the relevant pathway.</p>	<p><b><u>Cost pressure</u></b> Please specify:</p> <table border="1"> <thead> <tr> <th>Year 1 2018/19</th> <th>Year 2 2019/20</th> <th>Year 3 2020/21</th> <th>Year 4 2021/22</th> <th>Year 5 2022/23</th> </tr> </thead> <tbody> <tr> <td>£2,556,208</td> <td>£3,181,808</td> <td>£4,117,112</td> <td>£5,046,222</td> <td>£6,297,422</td> </tr> </tbody> </table>	Year 1 2018/19	Year 2 2019/20	Year 3 2020/21	Year 4 2021/22	Year 5 2022/23	£2,556,208	£3,181,808	£4,117,112	£5,046,222	£6,297,422		
Year 1 2018/19	Year 2 2019/20	Year 3 2020/21	Year 4 2021/22	Year 5 2022/23									
£2,556,208	£3,181,808	£4,117,112	£5,046,222	£6,297,422									
<p>C3.2 If the budget impact on NHS England cannot be identified set out the reasons why this cannot be measured.</p>	<p>Not Applicable</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>Not Applicable</p>												
<p><b>C4 Overall cost impact of this policy to the NHS as a whole</b></p>													
<p>C4.1 Specify the budget impact of the proposal on other parts of the NHS.</p>	<p>Budget impact for CCGs: <b><u>Cost saving</u></b></p> <table border="1"> <thead> <tr> <th></th> <th>Year 1 2018/19</th> <th>Year 2 2019/20</th> <th>Year 3 2020/21</th> <th>Year 4 2021/22</th> <th>Year 5 2022/23</th> </tr> </thead> <tbody> <tr> <td>Saving</td> <td>-£154,000</td> <td>-£656,250</td> <td>-£971,250</td> <td>-£1,414,500</td> <td>-£1,899,000</td> </tr> </tbody> </table> <p>Budget impact for providers: <b><u>Cost neutral</u></b> Please specify:</p>		Year 1 2018/19	Year 2 2019/20	Year 3 2020/21	Year 4 2021/22	Year 5 2022/23	Saving	-£154,000	-£656,250	-£971,250	-£1,414,500	-£1,899,000
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Saving	-£154,000	-£656,250	-£971,250	-£1,414,500	-£1,899,000								

	<p>It is anticipated that the procedure will reduce the incidence of ischaemic strokes and therefore reduce the long term care required for patients who would have had a stroke without the intervention. Atrial fibrillation and hypertension are the main risk factors for stroke. Prevention strategies have the potential to reduce 80% of strokes. Optimal treatment for AF has the potential to prevent stroke. The left atrial appendage is the source of 91% of thrombi in AF. The average cost of stroke is about 45k per patient over 5 years (Stoke Association (<a href="https://www.stroke.org.uk/sites/default/files/state_of_the_nation_2017_final_1.pdf">https://www.stroke.org.uk/sites/default/files/state_of_the_nation_2017_final_1.pdf</a>)). Hence it is expected that the procedure will be cost saving.</p>															
C4.2 Taking into account responses to C3.1 and C4.1, specify the budget impact to the NHS as a whole.	<p><b><u>Cost pressure</u></b> Please specify:</p> <table><tr><td></td><td><b><u>Cost pressure</u></b> Please specify:</td></tr><tr><td></td><td><table><tr><td>Year 1 2018/19</td><td>Year 2 2019/20</td><td>Year 3 2020/21</td><td>Year 4 2021/22</td><td>Year 5 2022/23</td></tr><tr><td>Cost</td><td>£2,402,208</td><td>£2,525,558</td><td>£3,145,862</td><td>£3,631,722</td><td>£4,398,422</td></tr></table></td></tr></table>		<b><u>Cost pressure</u></b> Please specify:		<table><tr><td>Year 1 2018/19</td><td>Year 2 2019/20</td><td>Year 3 2020/21</td><td>Year 4 2021/22</td><td>Year 5 2022/23</td></tr><tr><td>Cost</td><td>£2,402,208</td><td>£2,525,558</td><td>£3,145,862</td><td>£3,631,722</td><td>£4,398,422</td></tr></table>	Year 1 2018/19	Year 2 2019/20	Year 3 2020/21	Year 4 2021/22	Year 5 2022/23	Cost	£2,402,208	£2,525,558	£3,145,862	£3,631,722	£4,398,422
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Cost	£2,402,208	£2,525,558	£3,145,862	£3,631,722	£4,398,422											
C4.3 Where the budget impact is unknown set out the reasons why this cannot be measured																
C4.4 Are there likely to be any costs or savings for non-NHS commissioners and/or public sector funders?	<p><b><u>Yes</u></b> Please specify: Social care and community care costs savings and disability benefits.</p>															
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 funding will be from within the CPAG Prioritisation reserve
<b>C6 Financial Risks Associated with Implementing this Policy</b>	
C6.1 What are the material financial risks to implementing this policy?	There is a risk that the population to be treated has been under estimated.
C6.2 How can these risks be mitigated?	By careful assessment and screening processes for screening patients and strict application of commissioning criteria to select patients who will benefit the most from the LAAO. Also by national procurement of the LAAO device
C6.3 What scenarios (differential assumptions) have been explicitly tested to generate best case, worst case and most likely total cost scenarios?	The number of patients modelled is based on the low range (1000) to the high range (2500) of the expected patient cohort. If the number of patients were at the higher end of the range, the budget impact would increase by c£9m per year at full capacity (year 7).
C6.4 What scenario has been approved and why?	The lower end of the expected cohort has been modelled as this is the most likely number of patients each year (excluding backlog).
<b>C7 Value for Money</b>	
C7.1 What published evidence is available that the treatment is cost effective as evidenced in the evidence review?	To be completed once the CtE Economic results have been published
C7.2 Has other data been identified through the service specification development relevant to the assessment of	<i>Select all that apply:</i> _____



value for money?	Available pricing data suggests the treatment is equivalent cost compared to current/comparator treatment	<input type="checkbox"/>
	Available pricing data suggests the treatment is lower cost compared to current/comparator treatment	<input type="checkbox"/>
	Available clinical practice data suggests the new treatment has the potential to improve value for money	<input type="checkbox"/>
	Other data has been identified	<input type="checkbox"/>
	No data has been identified	<input type="checkbox"/>
	The data supports a high level of certainty about the impact on value	<input type="checkbox"/>
	The data does not support a high level of certainty about the impact on value	<input type="checkbox"/>
<b>C8 Cost Profile</b>		
C8.1 Are there non-recurrent capital or revenue costs associated with this policy?	<b><u>No</u></b>	
C8.2 If yes, confirm the source of funds to meet these costs.	Not applicable	