Integrated Impact Assessment Report for Clinical Commissioning Policies			
Policy Reference Number	1770		
Policy Title	Percutaneous patent foramen ovale closure for the prevention of recurrent cerebral embolic stroke Proposal **for routine commission**		
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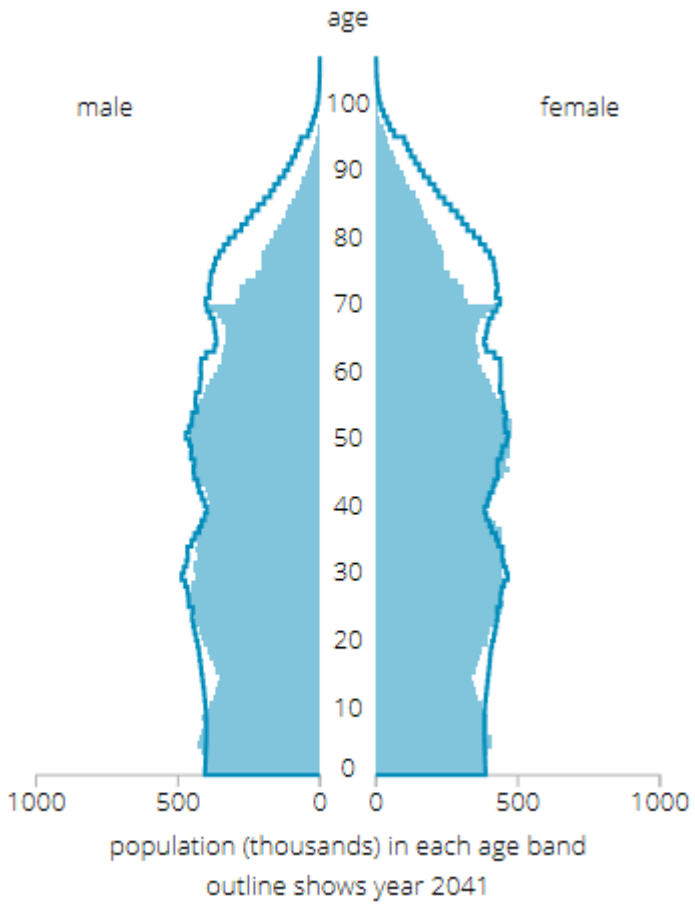
Integrated Impact Assessment – Index		
Section A – Activity	**Section B - Service**	**Section C – Finance**
A1 Current Patient Population & Demography / Growth	B1 Service Organisation	C1 Tariff
A2 Future Patient Population & Demography	B2 Geography & Access	C2 Average Cost per Patient **£TBA**
A3 Activity	B3 Implementation	C3 Overall Cost Impact of this Policy to NHS England **£TBA**
A4 Existing Patient Pathway	B4 Collaborative Commissioning	C4 Overall cost impact of this policy to the NHS as a whole **£TBA**
A5 Comparator (next best alternative treatment) Patient Pathway		C5 Funding
A6 New Patient Pathway		C6 Financial Risks Associated with Implementing this Policy **£TBA**
A7 Treatment Setting		C7 Value for Money
A8 Coding		C8 Cost Profile
A9 Monitoring		

About this Impact Assessment: instructions for completion and explanatory notes
• 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.	Approximately 25% of people have a foramen ovale which remains fully or partially open into adulthood (NICE IPG 472). In the UK, there are over 100,000 strokes each year, of which 85% are ischaemic (Stroke Association 2018). PFO is the most common association (40-50%) of cryptogenic stroke in patients younger than 55 years (Gonzalez-Alujas et al 2011, Tobis et al 2005). The lack of patient modifiable risk factors for cryptogenic stroke leads clinicians and patients to seek to modify risk factors such as PFO in order to reduce the risk of recurrence, in particular for patients who are unable to reduce their overall risk of stroke themselves (Li et al 2015). *Source: NICE IPG 472, Gonzalez-Alujas et al 2011, Tobis et al 2005 and Li et al 2015.*
A1.2 Number of patients currently eligible for the treatment according to the proposed policy commissioning criteria.	1500. Phasing is 800 patients in year 1 rising to 1500 in year 5 *plus ONS growth* *Source: Epidemiology and clinical experience of the procedure PRIOR to and during CtE.*
A1.3 Age group for which the treatment is proposed according to the policy commissioning criteria.	**Adults** 18 years and over
A1.4 Age distribution of the patient population eligible according to the proposed policy commissioning criteria	Patients between 18 and 60 years old *Source:* No trials involved patients above the age of 60. There is no persuasive body of evidence to support the use of PFO closure in patients with cryptogenic stroke over the age of 60 and indeed as this age range is reached the probability that stroke is due to occult / non-stenotic atheroma or AF rises substantially.

A1.5 How is the population currently distributed geographically?	**Evenly** If unevenly, estimate regional distribution by %: North Midlands & East London South *Source: The 2016 ONS population figures continue to show that there continues to be an increase in the aging population:* Please specify 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. However, although growth will be seen in the groups between 18 and 60 (the groups covered by this policy proposition) they are not projected to grow as quickly. Therefore, although there will be growth in absolute terms, the share of this age group of the total population is not projected to increase as significantly.



Source: Office for National Statistics National Population Projections: 2016-based statistical bulletin 2017

A2 Future Patient Population & Demography

<table>
<tr><td>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?</td><td><u>Increasing</u>
Source: The 2016 ONS population figures continue to show that there continues to be an overall increase in the population.</td></tr>
<tr><td>A2.2 Are there likely to be changes in demography of the patient population and would this impact on activity/outcomes?</td><td><u>No</u></td></tr>
<tr><td>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?

Are these numbers in line with ONS growth assumptions for the age specific population? If not please justify the growth assumptions made.</td><td><table><tr><td>YR2 +/-</td><td>11</td></tr><tr><td>YR3 +/-</td><td>14</td></tr><tr><td>YR4 +/-</td><td>15</td></tr><tr><td>YR5 +/-</td><td>17</td></tr><tr><td></td><td></td></tr></table>Source: Policy proposition and financial costing model

<u>Yes</u>
There will be a phasing of actual patients treated in years 1-3 due to the 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. Year 1 is assumed to be limited to 800 patients, year 2 1,100 and then 1,500 plus growth from Year 3 onwards in line with ONS population growth.</td></tr>
<tr><td colspan="2">A3 Activity</td></tr>
<tr><td>A3.1 What is the purpose of new policy?</td><td><u>Revise existing policy (expand or restrict an existing treatment threshold)</u></td></tr>
</table>

<table>
<tr><td></td><td>Please specify
NHSCB/A09/PS/a Patent Foramen Ovale (PFO) Closure
Dated April 2013. The aim is to reduce the risk of recurrent cerebral embolic stroke.</td></tr>
<tr><td>A3.2 What is the annual activity associated with the existing pathway for the eligible population?</td><td>None
Please specify
Procedure is not currently routinely commissioned</td></tr>
<tr><td>A3.3 What is the estimated annual activity associated with the proposed policy proposition pathway for the eligible population?</td><td>It is estimated that each patient will require the activity in the table below with the number of patients being 800 in year 1 rising to 1529 in year 5
<table>
<tr><th>Activity</th><th>Count</th></tr>
<tr><td>TBC</td><td>TBC</td></tr>
<tr><td></td><td></td></tr>
<tr><td></td><td></td></tr>
<tr><td></td><td></td></tr>
<tr><td></td><td></td></tr>
<tr><td></td><td></td></tr>
<tr><td></td><td></td></tr>
</table></td></tr>
<tr><td>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.</td><td>Not applicable</td></tr>
<tr><td colspan="2">A4 Existing Patient Pathway</td></tr>
</table>

A4.1 **Existing pathway:** Describe the relevant currently routinely commissioned: • Treatment or intervention • Patient pathway • Eligibility and/or uptake estimates.	Current treatments include anti-platelet or, in some cases, anti-coagulation medication. Surgical PFO closure in isolation is not considered clinically appropriate, although it can be undertaken as an addition to other open heart surgery.
A4.2. What are the current treatment access and stopping criteria?	Not applicable
A4.3 What percentage of the total eligible population is expected to: 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?	Not applicable
A5 Comparator (next best alternative treatment) Patient Pathway (NB: comparator/next best alternative does not refer to current pathway but to an alternative option)	
A5.1 **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**

A5.2 What percentage of the total eligible population is estimated to: 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?	Not applicable
A6 New Patient Pathway	
A6.1 What percentage of the total eligible population is expected to: 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?	If not known, please specify a) 15 % b) 6% c) 6% d) 6% e) 6% If total eligible population is patients with a previous stroke: 15% of strokes are cryptogenic and 40% of these will be found to have a PFO (6%)
A6.2 Specify the nature and duration of the proposed new treatment or intervention.	**Time limited** For time limited treatments, specify frequency and/or duration. The procedure is usually carried out under local/general anaesthetic with the use of transoesophageal or intracardiac echocardiographic and fluoroscopy guidance. It requires placement of a catheter in the right femoral vein so that the device can be passed to the heart. It is then positioned across the PFO and deployed so that both ends of the channel are blocked. The duration of the procedure is approximately one hour. Transthoracic echocardiography should be performed prior to patient

<table>
<tr><td></td><td>discharge to exclude any complications of the procedure. Anti-platelet, or in some patient's anti-coagulant drugs will usually be continued for 6 months post procedure and long term aspirin is often indicated.</td></tr>
<tr><td colspan="2">A7 Treatment Setting</td></tr>
<tr><td>A7.1 How is this treatment delivered to the patient?</td><td>Select all that apply:
<table><tr><td>Emergency/Urgent care attendance</td><td>☐</td></tr><tr><td>Acute Trust: inpatient</td><td>☒</td></tr><tr><td>Acute Trust: day patient</td><td>☒</td></tr><tr><td>Acute Trust: outpatient</td><td>☒</td></tr><tr><td>Mental Health provider: inpatient</td><td>☐</td></tr><tr><td>Mental Health provider: outpatient</td><td>☐</td></tr><tr><td>Community setting</td><td>☐</td></tr><tr><td>Homecare</td><td>☐</td></tr><tr><td>Other</td><td>☐</td></tr></table></td></tr>
<tr><td>A7.2 What is the current number of contracted providers for the eligible population by region?</td><td><table><tr><td>NORTH</td><td>0</td></tr><tr><td>MIDLANDS & EAST</td><td>0</td></tr><tr><td>LONDON</td><td>0</td></tr><tr><td>SOUTH</td><td>0</td></tr></table>The are no commissioned providers of the service</td></tr>
</table>

A7.3 Does the proposition require a change of delivery setting or capacity requirements?	**yes** Please specify: A national procurement intervention will be required to commission specialised/ tertiary cardiac centres to deliver the service.
A8 Coding	
A8.1 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: Funding of £100k per year for a National Registry has been included in the Impact Assessment and finance model.

<table>
<tr>
<td>A8.2 Specify how the activity related to the new patient pathway will be identified.</td>
<td>Select all that apply:
<table>
<tr><td>OPCS v4.8</td><td>☒</td></tr>
<tr><td>ICD10</td><td>☒</td></tr>
<tr><td>Treatment function code</td><td>☒</td></tr>
<tr><td>Main Speciality code</td><td>☐</td></tr>
<tr><td>HRG</td><td>☒</td></tr>
<tr><td>SNOMED</td><td>☐</td></tr>
<tr><td>Clinical coding / terming methodology used by clinical profession</td><td>☐</td></tr>
</table>
</td>
</tr>
<tr>
<td>A8.3 Identification Rules for Drugs:
How are drug costs captured?</td>
<td><u>Not applicable</u>
If the drug has already been specified in the current NHS England Drug List please specify drug name and drug indication:

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:</td>
</tr>
<tr>
<td>A8.4 Identification Rules for Devices:
How are device costs captured?</td>
<td><u>Already covered by an existing category of HCTED but not commissioned via the Zero Cost Model</u>
If the device is covered by an existing category of HCTED please specify the Device Category (as per the National Tariff Payment System Guidance).
Occluder Vascular Appendage and septal devices</td>
</tr>
</table>

A8.5 **Identification Rules for Activity:** How are activity costs captured?	**Already correctly captured by an existing specialised service line (NCBPS code within the PSS Tool** If activity costs are already captured please specify the specialised service code and description (e.g. NCBPS01C Chemotherapy). NCBPS13X - Congenital Heart Disease (Adults) If activity costs are already captured please specify whether this service needs a separate code. **No** 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. No If the activity is not captured please specify whether the proposed identification rules have been documented and agreed with the Identification Rules team. **No**
A9 Monitoring	
A9.1 **Contracts** Specify any new or revised data flow or data collection requirements, needed for inclusion in the NHS Standard Contract Information Schedule.	**None**
A9.2 **Excluded Drugs and Devices (not covered by the Zero Cost Model)** 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:* Drugs or Device MDS ☒ Blueteq ☒ Other prior approval ☐

A9.3 **Business intelligence** Is there potential for duplicate reporting?	**No**
A9.4 **Contract monitoring** Is this part of routine contract monitoring?	**Yes** If yes, please specify contract monitoring requirement: Activity will be reported in line with Schedule 6 of the NHS Standard Contract
A9.5 **Dashboard reporting** Specify whether a dashboard exists for the proposed intervention?	**No** If yes, specify how routine performance monitoring data will be used for dashboard reporting. If no, will one be developed? Data will be collected through a National Registry
A9.6 **NICE reporting** Are there any directly applicable NICE or equivalent quality standards which need to be monitored in association with the new policy?	**No**
Section B - Service Impact	
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 *Source:* Clinical Commissioning Policy Statement: Patent Foramen Ovale (PFO) Closure April 2013 Reference: NHSCB/A09/PS/a

<table>
<tr><td>B1.2 Will the proposition change the way the commissioned service is organised?</td><td><u>Yes</u>
Please specify:
Providers will be selected to provide the service when commissioned.</td></tr>
<tr><td>B1.3 Will the proposition require a new approach to the organisation of care?</td><td><u>No change to delivery of care</u>
Please specify:
Service delivery will be through current specialised cardiac interventional services. A lead in period will be required to build capacity to deliver the service and increase awareness and education of health professionals in primary and secondary care.</td></tr>
<tr><td colspan="2">B2 Geography & Access</td></tr>
<tr><td>B2.1 Where do current referrals come from?</td><td>Select all that apply:<table><tr><td>GP</td><td>☐</td></tr><tr><td>Secondary care</td><td>☒</td></tr><tr><td>Tertiary care</td><td>☒</td></tr><tr><td>Other</td><td>☐</td></tr></table></td></tr>
<tr><td>B2.2 What impact will the new policy have on the sources of referral?</td><td><u>No impact</u></td></tr>
<tr><td>B2.3 Is the new policy likely to improve equity of access?</td><td><u>No impact</u>

Source: Equalities Impact Assessment</td></tr>
</table>

B2.4 Is the new policy likely to improve equality of access and/or outcomes?	**No impact** Please specify: The new policy is likely to provide recurrent stroke prevention to patients with a clinically significant PFO who are at high risk of recurrent stroke. *Source: NHSCB/A09/PS/a Clinical Commissioning Policy Statement: Patent Foramen Ovale (PFO) Closure* *Dated April 2013*
B3 Implementation	
B3.1 Will commissioning or provider action be required before implementation of the proposition can occur?	**Procurement action** Please specify: There are currently no commissioned providers; a national procurement intervention will be required to commission centres to deliver the service.
B3.2 **Time to implementation:** Is a lead-in time required prior to implementation?	**Yes - go to B3.3** If yes, specify the likely time to implementation: 12 months
B3.3 **Time to implementation:** If lead-in time is required prior to implementation, will an interim plan for implementation be required?	**Yes** If yes, outline the plan: An interim plan will be required. The criteria for this will need to be decided but may follow the example of LAAO and utilise the centres which were involved in the CtE programme.
B3.4 Is a change in provider physical infrastructure required?	**No** Please specify: The procedure can be delivered within current tertiary and specialised cardiac facilities

<table>
<tr><td>B3.5 Is a change in provider staffing required?</td><td><u>Yes</u>
Please specify:
There may be a requirement to increase staff to deliver the new procedure</td></tr>
<tr><td>B3.6 Are there new clinical dependency and/or adjacency requirements that would need to be in place?</td><td><u>No</u>
Please specify:
All the specialities within a tertiary cardiac and cardiothoracic centre in line with current specialised cardiology service specifications.</td></tr>
<tr><td>B3.7 Are there changes in the support services that need to be in place?</td><td><u>No</u></td></tr>
<tr><td>B3.8 Is there a change in provider and/or inter-provider governance required? (e.g. ODN arrangements / prime contractor)</td><td><u>No</u>
Please specify:
Services are not currently commissioned</td></tr>
<tr><td>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</td><td><u>Increase</u>
Please complete table:
<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>5</td><td><u>P</u></td></tr>
<tr><td>Midlands & East</td><td>0</td><td>5</td><td><u>P</u></td></tr>
<tr><td>London</td><td>0</td><td>5</td><td><u>P</u></td></tr>
<tr><td>South</td><td>0</td><td>5</td><td><u>P</u></td></tr>
<tr><td>Total</td><td>0</td><td>20</td><td><u>P</u></td></tr>
</table></td></tr>
</table>

<table>
<tr><td></td><td>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.</td></tr>
<tr><td>B3.10 Specify how revised provision will be secured by NHS England as the responsible commissioner.</td><td>Select all that apply:
<table><tr><td>Publication and notification of new policy</td><td>☒</td></tr><tr><td>Market intervention required</td><td>☒</td></tr><tr><td>Competitive selection process to secure increase or decrease provider configuration</td><td>☐</td></tr><tr><td>Price-based selection process to maximise cost effectiveness</td><td>☐</td></tr><tr><td>Any qualified provider</td><td>☐</td></tr><tr><td>National Commercial Agreements e.g. drugs, devices</td><td>☒</td></tr><tr><td>Procurement</td><td>☒</td></tr><tr><td>Other</td><td>☐</td></tr></table>Please specify:
Future provision will be secured through procurement. The device will need to be included in the HCTED programme.</td></tr>
<tr><td colspan="2">B4 Place-based Commissioning</td></tr>
<tr><td>B4.1 Is this service currently subject to, or planned for, place-based commissioning arrangements? (e.g. future CCG lead, devolved commissioning arrangements, STPs)</td><td><u>No</u></td></tr>
</table>

Section C - Finance Impact

C1 Tariff/Pricing

C1.1 How is the service contracted and/or charged?
Only specify for the relevant section of the patient pathway

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	☐
	Excluded from tariff (excluding ZCM) – pass through	☒
	Excluded from tariff (excluding ZCM) – other	☐
	Via Zero Cost Model	☐
Activity	Paid entirely by National Tariffs	☒
	Paid entirely by Local Tariffs	☐
	Partially paid by National Tariffs	☐
	Partially paid by Local Tariffs	☐
	Part/fully paid under a Block arrangement	☐
	Part/fully paid under Pass-Through arrangements	☐
	Part/fully paid under Other arrangements	☐

C1.2 **Drug Costs**
Where not included in national or local tariffs, list each drug or combination, dosage, quantity, **list** price

Not applicable

<table>
<tr><td>including VAT if applicable and any other key information e.g. Chemotherapy Regime.
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
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.</td><td>£3,295 per device exclusive of VAT</td></tr>
<tr><td>C1.4 Activity Costs covered by National Tariffs
List all the HRG codes, HRG descriptions, national tariffs (excluding MFF), volume and other key costs (e.g. specialist top up %)</td><td><table><tr><th>Activity</th><th>Cost (£)</th></tr><tr><td>TBC</td><td>TBC</td></tr><tr><td></td><td></td></tr><tr><td></td><td></td></tr><tr><td></td><td></td></tr><tr><td></td><td></td></tr></table></td></tr>
<tr><td>C1.5 Activity Costs covered by Local Tariff
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.</td><td>Not applicable</td></tr>
</table>

<table>
<tr><td>C1.6 Other Activity Costs not covered by National or Local Tariff
Include descriptions and estimates of all key costs.</td><td>Not applicable</td></tr>
<tr><td>C1.7 Are there any prior approval mechanisms required either during implementation or permanently?</td><td><u>No</u></td></tr>
<tr><td colspan="2">C2 Average Cost per Patient</td></tr>
<tr><td>C2.1 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?</td><td><table>
<tr><td>YR1</td><td>£TBC</td></tr>
<tr><td>YR2</td><td>£TBC</td></tr>
<tr><td>YR3</td><td>£TBC</td></tr>
<tr><td>YR4</td><td>£TBC</td></tr>
<tr><td>YR5</td><td>£TBC</td></tr>
</table></td></tr>
<tr><td colspan="2">C3 Overall Cost Impact of this Policy to NHS England</td></tr>
<tr><td>C3.1 Specify the budget impact of the proposal on NHS England in relation to the relevant pathway.</td><td><u>Cost pressure</u><table>
<tr><td>YR1</td><td>£TBC</td></tr>
<tr><td>YR2</td><td>£TBC</td></tr>
<tr><td>YR3</td><td>£TBC</td></tr>
</table></td></tr>
</table>

C3.2 If the budget impact on NHS England cannot be identified set out the reasons why this cannot be measured.	Not applicable
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 applicable
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: **Cost saving** *The potential savings for CCGs will come from a reduction in the number of stroke procedures necessary.* Value £TBC Budget impact for providers: **Cost neutral** Please specify:
C4.2 Taking into account responses to C3.1 and C4.1, specify the budget impact to the NHS as a whole.	**Cost pressure** Please specify: Value £TBC

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?	**Yes** Please specify: Social care and community care cost savings and disability benefits.
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.
C6 Financial Risks Associated with Implementing this Policy	
C6.1 What are the material financial risks to implementing this policy?	There is a risk that the requirement for a building of capacity over time has been over estimated and that the anticipated numbers will present within a shorter timeframe i.e. within first 2 years.
C6.2 How can these risks be mitigated?	It is not clear how real this risk is as numbers in the CtE were less. However, the activity and finance modelling is based on best clinical knowledge of numbers of eligible patients and a consensus view, including that of the professional clinical body, of future impact. Additionally, by careful assessment and screening processes for patients and by the strict application of commissioning criteria to select patients who will benefit the most from the intervention. Inclusion of the PFO closure device in the national HCTED programme will enable device costs to be managed.

C6.3 What scenarios (differential assumptions) have been explicitly tested to generate best case, worst case and most likely total cost scenarios?	Click here to enter text.
C6.4 What scenario has been approved and why?	Click here to enter text.
C7 Value for Money	
C7.1 What published evidence is available that the treatment is cost effective as evidenced in the evidence review?	The ICERS reported by Tirschwell et al 2018 are well within the accepted £20,000 per QALY threshold at 10 and 20 years. However, it is possible that there remains some uncertainty about the cost-effectiveness of PFO closure compared with MTA due to the ambiguity of the UK subpopulation patient selection criteria, the lack of reported confidence intervals and the lack of other cost effectiveness outcomes including the cost per life year gained, the cost to prevent one recurrent stroke, or the time before the cost of medical therapy exceeds the cost of PFO closure. Further information will be provided by the CtE economic analysis Please specify: 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 value for money?	*Select all that apply:* Available pricing data suggests the treatment is equivalent cost compared to current/comparator treatment ☐ Available pricing data suggests the treatment is lower cost compared to current/comparator treatment ☐ Available clinical practice data suggests the new treatment has the potential to improve value for money ☒ Other data has been identified ☐ No data has been identified ☐

	The data supports a high level of certainty about the impact on value	☐
	The data does not support a high level of certainty about the impact on value	☐
C8 Cost Profile		
C8.1 Are there non-recurrent capital or revenue costs associated with this policy?	**No**	
C8.2 If yes, confirm the source of funds to meet these costs.	Not applicable	