

Clinical Commissioning Policy: Left Atrial Appendage Occlusion for patients with atrial fibrillation and relative or absolute contraindications to anticoagulation (adults)

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Clinical Commissioning Policy: Left Atrial Appendage Occlusion for patients with atrial fibrillation and relative or absolute contraindications to anticoagulation (Adults)

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**Prepared by NHS England Specialised Services Clinical Reference Group for
Cardiac Services**

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Policy Statement

NHS England will commission left atrial appendage occlusion to treat patients with non-valvular atrial fibrillation and absolute and relative contraindications to oral anticoagulants with percutaneous left atrial appendage occlusion in accordance with the criteria outlined in this document.

In creating this policy NHS England has reviewed this clinical condition and the options for its treatment. It has considered the place of this treatment in current clinical practice, whether scientific research has shown the treatment to be of benefit to patients, (including how any benefit is balanced against possible risks) and whether its use represents the best use of NHS resources.

This policy document outlines the arrangements for funding of this treatment for the population in England.

Equality Statement

Promoting equality and addressing health inequalities are at the heart of NHS England's values. Throughout the development of the policies and processes cited in this document, we have:

- given due regard to the need to eliminate discrimination, harassment and victimisation, to advance equality of opportunity, and to foster good relations between people who share a relevant protected characteristic (as cited under the Equality Act 2010) and those who do not share it; and
- given regard to the need to reduce inequalities between patients in access to, and outcomes from healthcare services and to ensure services are provided in an integrated way where this might reduce health inequalities.

Plain Language Summary

About Atrial Fibrillation

Atrial fibrillation (AF) is the most common cardiac arrhythmia (abnormal heart rhythm) seen in clinical practice. Some patients with AF may not experience symptoms relating to their arrhythmia whilst others may experience dizziness, shortness of breath or notice palpitations.

Due to the irregular contractions of the atrium (an upper chamber of the heart) in AF, blood is not effectively pumped out of the atrium and instead may pool and form clots (thrombus). The left atrial appendage (a small pouch/sac in the wall of the left atrium of the heart) is the site at which over 90% of these clots will occur. If a clot is then expelled from the heart it can enter the brain circulation, cause a blockage and lead to a disabling or even fatal stroke. AF is associated with a 5 times increased risk of stroke.

About current treatments

Treatment of AF patients with medication (oral anticoagulants or OACs) that slow or prevent the clotting of blood has been shown to reduce this risk of stroke. These medications are associated with the potential for severe bleeding complications. They would be unsuitable for patients with a history of severe haemorrhage or high bleeding risks. While these are the main considerations, there may be other reasons for unsuitability for OACs.

About the new treatment

Percutaneous occlusion of the left atrial appendage (LAAO) is aimed at closing off the left atrial appendage, thereby reducing the ability of clot formation and subsequent risk of a stroke.

What we have decided

NHS England has carefully reviewed the evidence to treat non-valvular atrial fibrillation and absolute and relative contraindications to oral anticoagulants with

percutaneous left atrial appendage occlusion. We have concluded that there is enough evidence to consider making the treatment available.

1 Introduction

Atrial fibrillation (AF) is the most common clinically relevant cardiac arrhythmia (abnormal heart rhythm). The estimated prevalence in the general population is 1-2% and increases with age. Some patients with AF may not experience symptoms relating to their arrhythmia whilst others may experience dizziness, shortness of breath or notice palpitations. Due to the irregular contractions of the atrium in AF, blood is not effectively pumped out of the atrium and instead may pool and form clot/s (thrombus/thrombi). Hence the reason for stroke in AF is cardio-embolic. If a thrombus enters the cerebral circulation, it may cause occlusion and lead to a disabling or even fatal stroke. AF is associated with a 5 times increased risk of stroke which tend to be ischaemic. Strokes related to AF are associated with a higher mortality and morbidity when compared with non-AF strokes, emphasizing the need for more effective stroke prevention in these patients. There is a clear relationship between the CHADS2 score, the CHA₂DS₂-VASc score and stroke rate and also the HAS-BLED score for bleeding risk that influence decisions for anticoagulant treatment choice.

Prospective and randomized studies show that oral anticoagulation significantly reduces the risk of thromboembolism and stroke by 68%. However, this treatment is underutilised in up to 40-50% of patients with AF due to poor patient compliance, contraindications and potential bleeding complications. Oral anticoagulation is aimed at reducing this risk of stroke by preventing thrombus formation but this in turn means that medications like warfarin are associated with the potential for severe haemorrhagic complications including intracerebral haemorrhage. Even with the newer direct oral anticoagulants (DOACs), the overall incidence of major bleeding may not be less than vitamin K antagonists (VKAs), however intracranial haemorrhage (ICH) rates may be lower while gastrointestinal bleeding may be more pronounced.

Hence current oral anticoagulant therapy options would likely be unsuitable for patients with a history of, or high risk of a major, or life threatening haemorrhage e.g. intracranial or gastroenterological haemorrhage. A history of spontaneous or

OAC- associated intracranial haemorrhage increases the risk of recurrent haemorrhage and devastating clinical consequences. Consequently, these patients are currently unprotected from the risk of stroke.

The left atrial appendage (LAA) is a small pouch/sac in the wall of the left atrium of the heart. It is recognised as a site where pooled blood may form and enable thrombus formation during the irregular contractions in non-valvular AF. The LAA is the most common site of thrombi (> 90%). Percutaneous occlusion of the left atrial appendage (LAAO) is aimed at closing off the appendage, thereby reducing the ability of thrombus formation and risk of thromboembolism.

The procedure is usually carried out under general anaesthetic with the use of 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.

NICE has published Interventional Procedure Guidance (IPG349) on its use which should be limited to units with on-site cardiac surgery. NICE guidance on the management of AF (CG180) recommends the consideration of LAAO in patients for whom oral anticoagulation therapy would be indicated based on stroke risk but in whom oral anticoagulants are contraindicated or not tolerated.

This policy describes the rationale for the use of LAAO for patients with non-valvular AF who have relative or absolute contraindications for oral anticoagulation and clinical and research governance requirements for future monitoring.

2 Definitions

Atrial fibrillation: This is a heart condition that causes an irregular heartbeat. It results from loss of co-ordinated contraction of the two atria – the upper receiving chambers of the heart. Non-valvular AF is AF which occurs in the absence of rheumatic mitral valve disease or a metallic mitral prosthesis.

Atrium: The heart is divided into four chambers that are connected by heart valves. The upper two heart chambers are called atria. Atria are separated by an interatrial septum into the left atrium and the right atrium.

CHADS2 score and CHA₂DS₂-VASc score: Calculates stroke risk for patients with atrial fibrillation.

Commissioning through Evaluation (CtE): An NHS England programme that enables a limited number of patients to access treatments that are not funded by the NHS, but nonetheless show significant promise for the future, while new clinical and patient experience data are collected within a formal evaluation programme.

Computerised Tomography (CT) Scan: imaging that makes use of computer processed combinations of x-ray measurements taken from different angles to produce cross-sectional images.

Direct Oral Anti-Coagulant medication (DOACs): A new oral anticoagulant.

Femoral vein: The femoral vein is located in the upper thigh and pelvic region of the human body.

Fibrin: A protein that is essential for proper blood coagulation.

Haemorrhagic complications: This is a complication involving a bleeding event.

HAS-BLED: The score for Major bleeding risk estimates risk of major bleeding for patients on anticoagulation to assess quality of atrial fibrillation care.

Left atrial appendage: The left atrial appendage is a small pouch in the left atrium. It is a site where blood clots predominantly form in atrial fibrillation.

Cardio-embolic stroke: This is a stroke that results from debris or a clot in the heart moving into the circulation and blocking a blood vessel supplying brain tissue. An ischaemic stroke is due to blockage of an artery that supplies blood

and oxygen to part of the brain. When this blockage is due to a clot that has travelled from the heart it is called cardio-embolic or thromboembolic.

Intracerebral Haemorrhage (ICH): A type of stroke caused by bleeding within the brain tissue itself.

Intracranial bleed: Bleeding within the skull.

Occlusion: The blockage or closing of a blood vessel or hollow organ.

Oral Anti-Coagulant (OAC): A substance that slows or prevents the clotting of blood.

Percutaneous: Performed through the skin.

Quality of Life (QOL): Is the perceived quality of an individual's daily life, that is, an assessment of their well-being or lack thereof.

Relative, absolute and contraindications for anticoagulation: A reason for not giving blood thinning medicines which is so overpowering or carries such a grave risk that its performance would be reasonably regarded as constituting malpractice.

Stenosis: An abnormal narrowing or contraction of a body passage or opening.

Thromboembolic: Formation in a blood vessel of a clot (thrombus) that breaks loose and is carried by the blood stream to plug another vessel.

Trans-septal catheterization: A method used to measure the left atrial and left ventricular pressure.

3 Aims and Objectives

This policy considered: the clinical criteria under which NHS England will routinely commission the LAAO procedure for patients with non-valvular AF who have relative or absolute contraindications to anticoagulation

The objectives were to:

- determine the clinical effectiveness and safety of LAAO in the prevention of stroke in patients with AF at high risk of stroke and who have relative or absolute clinical contraindication/s to the use of oral anticoagulant therapies
- determine the patient eligibility criteria for the LAAO device, ensuring the best clinical and cost-effective use and taking account of patient risk stratification
- ensure robust monitoring and follow up arrangements to enable audit of stroke/other thromboembolic event rate and procedure/device related complications.

4 Epidemiology and Needs Assessment

The prevalence of diagnosed AF is 1.7% (QOF Report, 2015-16). About 83% of patients with CHADS2 (old scoring system) of >1 are eligible for stroke prevention treatment, usually with oral anticoagulants.

The number of patients with contraindications will vary widely depending on criteria threshold. Many patients are not treated, but reasons for this may include physician or patient decisions or error rather than a formal contraindication. It is estimated that 6% of diagnosed AF patients have contraindications to OAC (Adderley N et al. 2017).

Hence it can be estimated that in a population of 53 million (England) there are 800,000 diagnosed with AF of which 664,000 have a risk profile requiring treatment and 40,000 have contraindications to OAC. However many patients will be near end of life or have comorbidities that make LAAO unsuitable due to the risks of the procedure, or may decide they don't want the treatment.

It is estimated that eventually 10% of LAAO-eligible patients will be referred for possible LAAO, as referral networks become established, but this will take >5 years.

If approved, it is estimated that initial case volume would be 400 per annum, building up to 1000 per annum in 5 years' time.

5 Evidence Base

NHS England has concluded that there is sufficient evidence to support a proposal for the routine commissioning of this treatment for the indication.

NHS England expects to receive an additional analysis from the National Institute for Health and Care Excellence (NICE) in autumn 2018. This will specifically analyse data on mortality and other outcomes available from hospital episode statistics (HES) and the Office of National Statistics (ONS) and linked to patients treated as part of the Commissioning through Evaluation (CtE) scheme to gain a greater understanding of the safety and efficacy of this procedure. Should these findings materially change NHS England's understanding of balance of risks and benefits of this procedure, the policy may be reviewed or refined accordingly.

SUMMARY OF EVIDENCE REVIEW

The following summary is abstracted from the externally commissioned evidence review by NICE, for the purposes of the policy proposition. For full details of the evidence and the references, please refer to the full evidence review.

Fourteen studies (presented in 20 publications) met the inclusion criteria for **clinical effectiveness and adverse events** (Berti et al. 2016, Betts et al. 2017, Boersma et al. 2016a, Boersma et al. 2016b, Figini et al. 2017, Koskinas et al. 2016, Lopez Minguéz et al. 2015, Reddy et al. 2013, Santoro et al. 2016, Seeger et al. 2016, Tzikas et al. 2016, Bergmann et al. 2017, Boersma et al. 2017, Freixa et al. 2016, Huang et al. 2017, Lempereur et al. 2017b, Meerkin et al. 2013, Murarka et al. 2017, Saw et al. 2017, Tzikas et al. 2017). All of these studies were registry or observational studies; no randomised controlled studies were identified that met the inclusion criteria.

Two further studies informed the analysis of **cost effectiveness** (Panikker et al. 2016, Reddy et al. 2016).

Clinical effectiveness and adverse events:

The 14 included registry or observational studies ranged in size from 100 to 1,047 patients. These studies reported on various procedure and device-related adverse events (typically ≤ 7 days), as well as follow-up complications and adverse events (with a follow-up duration that ranged from 210.3 [SD 182.2] days to 30 [SD 12] months [264 patient-years] across the studies).

These studies show that LAAO with various devices (Watchman, ACP, Amulet) is associated with a moderate number of peri-procedural complications and low adverse events. The most frequent peri-procedural events were minor pericardial effusion and bleeding. The most frequent complications associated with LAAO devices in the long-term included stroke, bleeding, device-related thrombus and leaks. The percentages of patients with various complications and adverse events is described in detail in Section 4 below.

In terms of stroke, the percentage of patients who experienced peri-procedural stroke was reported in eleven studies and ranged from 0% to 1.2% across these studies. Three studies reported on ischaemic stroke, which ranged from 0% to 1%. The remaining studies did not report on peri-procedural stroke.

All-cause stroke or embolism at follow-up was reported in six studies and ranged from 0% (reported at a mean follow-up of 210.3 ± 182.2 days) to 4.5% (reported at a mean follow-up of 30 ± 12 months). Rates ranged from 1.6 per 100 patient-years to 2.3% per year. Eight studies reported on ischaemic or haemorrhagic stroke. The percentages of patients with ischaemic stroke ranged from 0% (reported at a mean follow-up of 448 (167-793) days) to 2% (reported at a mean follow-up of 400 days). Rates of ischaemic stroke ranged from 0.57 per 100 patient-years to 2.2% per year and rates of haemorrhagic stroke ranged from 0.28 per 100 patient-years to 0.6% per year.

Many of the authors of these registry and observational studies concluded that LAAO appeared to be safe and effective in patients for whom anticoagulation

therapy is contraindicated. However, given that these studies are inherently limited by the lack of a control group and had other methodological issues, the results presented by the study authors (as summarised in this evidence review) should be considered with caution and need to be confirmed with data from randomised controlled trials.

Cost-effectiveness:

Results from both studies suggest that LAAC provides long-term clinical and economic benefits when compared with aspirin; one study (Panikker et al. 2016) found that LAAO was also cost saving after year 7 compared with no therapy.

The Panikker (2016) study was a high quality cost study set in England, with good internal validity but poor external validity. The second, slightly weaker study, set in Germany, also lacked external validity (Reddy et al. 2016).

CONCLUSIONS FROM THE EVIDENCE REVIEW

The evidence review based on 14 registry/observational studies, suggests that LAAO in patients contraindicated to oral anticoagulants appears to be safe and effective. All of these studies are registry or observational studies covering a total population of 4200 patients. Two of the studies are very large and include over a thousand patients each (EWOLUTION, ACP). Arguably they are inherently limited by the lack of a control group. Hence any relevant comparisons of outcomes can only be made with historical data.

Further research from RCTs will be needed to confirm the current results of these registry studies. Key research findings include the following:

- The most frequent clinical indications for LAAO in patients at high risk of stroke/thromboembolic events included a history of major bleeding events, a high risk/predisposition to bleeding and secondary prevention following occurrence of significant thromboembolic events on OACs.
- Procedural success for the LAAO device was high and ranged from 88.3% to 100%.
- The devices most researched were the Watchman and the Amplatzer.

- Mean age of patients ranged between 64 to 77 years, and the majority of patients were males. Where reported, the mean CHA₂DS₂-VASc score ranged between 3.6 (SD 1.6) and 4.6 (SD 1.4), and the mean HAS-BLED score ranged between 2.3 (SD 1.2) and 4.2 (SD 1.3).
- Peri-procedural and follow-up rates of thromboembolic events (stroke, TIA, systemic embolism) following LAAO appeared to be low.
- Rates of ischaemic stroke after LAAO were reduced to 0 - 2.0% a year. In the EWOLUTION Registry one year follow up, the rate of ischaemic stroke was 1.1 %, whereas the expected incidence of an ischaemic stroke or thromboembolic (stroke/TIA/peripheral embolism) event with a CHA₂DS₂-VASc score of 4 from historical data was 6.8% to 9.3% (Friberg et al. 2012).
- Death rates on follow-up could be up to 12%. However this may reflect the advanced age and other co-morbidities characteristics of the population implanted. This emphasises the importance of patient selection.
- There is a risk of bleeding circa 5% seen both peri-procedurally and during follow-up. This may reflect the relative background bleeding risk. In the two largest registries the risk of major bleeding was half this figure.
- Procedure and device-related complications included pericardial effusion, cardiac tamponade, air embolism, device thrombosis and leaks. Their individual frequencies were low and ranged from 0-3% a year. The reported frequency of device-related thrombus and leaks tended to be higher.
- There is beneficial evidence of a learning curve on the improvement of clinical outcomes. Overall, procedural success and safety increased with operator and centre experience.

SUMMARY OF COMMISSIONING THROUGH EVALUATION

The Commissioning through Evaluation (CtE) scheme for LAAO commenced on 1/10/2014 and ran for two years. It was a procedural registry with no comparator arm. Data was collected prospectively and patients were followed up for two years.

Ten specialised cardiology and cardiac surgery centres participated. The evaluation was carried out by NICE in collaboration with the Cardiology CtE Steering Group which is a subgroup of the Cardiothoracic Clinical Reference Group (CRG). The latter with NICOR was responsible for the design and methodology.

On completion of the CtE, 571 LAAO procedure records were extracted, of which 46 patients did not meet the eligibility criteria and were excluded. 525 were available for analysis.

The aim of the CtE was to generate new evidence from real world acute clinical settings to enable a judgement on clinical and cost-effectiveness of LAAO in the identified population.

Results

Risk Profile of Patients

The patients in the CtE Registry had a median CHA₂DS₂-VASc score of 4 and median HASBLED score of 4. This is comparable with the other registries median CHA₂DS₂-VASc scores ranging from 4.2- 4.4. However the HAS-BLED scores for the latter were lower ranging from 2 to 3.3.

Success Rates:

Short -term

Technical success rates reported were 93.6% (95% CI 91.1% to 95.6%). Procedural success (defined as technical success in the absence of major complication) was reported as 89.0% (95% CI 86.0% to 91.6%). 99.3% had no or minor peri- device leak). Only two patients had a major leak. Clinical failure (device not implanted, large leak, neurological event before discharge) was reported in 9.1%. There was an in hospital major complication rate of 5.5%. The rate of procedural mortality was low (1%) with a reported neurological event rate of 0.8%. These outcomes were consistent with the published literature.

Medium –term

During follow-up 25 patients died – 19 of these 25 deaths were unrelated to the procedure or its indication. 19 patients had a neurological event during follow-up. 10

patients had ischaemic neurological events, giving a rate of 2.6 per 100 patient years. CtE did not provide any evidence for additional safety concerns.

Reduction in risk of stroke/embolic clinical events

Most patients in the CtE (circa 300) had a CHA₂DS₂-VASc score between 3 and 6, with 85 between 2-3. The median CHA₂DS₂-VASc score was 4 with a predicted risk of a thromboembolic event of 6.7% to 9.3% per year. This can be compared with the actual CtE incidence of 2.6% per year.

Length of Stay

This was a median of 1 overnight stay. However, nearly a quarter of procedures resulted in an extended length of stay of ≥ 2 nights.

QOL

Quality of life (QoL) was measured at baseline and at follow up (6 weeks, 6 months, 1 year and 2 years) using the EuroQol system (EQ-5D-5L), converted to utility scores. The median baseline utility was 0.82. This improved to 0.85 at both 6 weeks and 6 months and reduced slightly to 0.84 at one and two years. These changes were not statistically significant. However the domain that demonstrated the greatest benefit from the procedure was a reduction in anxiety and depression.

Long term cardiac complications (e.g. penetration of arterial/atrial walls).

There were none noted in the CtE. Whilst this has to be noted in the context of the limited follow-up, this finding is consistent with the literature.

Reasons (and demand) for LAAO treatment

Just under a quarter of patients had previous bleeding without anticoagulant therapy. Nearly 60 percent had previous bleeding with anticoagulant therapy. 7.1 % were at risk of severe bleeding. These three categories amounted to 88% of requests. These categories equalled 83% in another UK registry by Betts. Other reasons included intolerance (majority)/poor control) of oral anticoagulants; primary or secondary prophylaxis and patient preference.

The associated literature review suggested that 2% of patients with AF had an absolute contraindication to warfarin use, with 60% having a history of ICH. Another study showed that 13% of patients eligible for oral anticoagulation had a major contraindication to warfarin.

LAAO devices used

Thirty eight (38%) percent of devices used were Watchman with the Amplatzer Amulet accounting for 47%. The Amplatzer cardiac plug was used in 35 (8%) cases. There were no significant differences seen between devices in terms of superior technical or procedural success or death and neurological events.

Sub-group differences

No significant differences for outcomes were seen for age or gender.

Conclusions from CtE

- The CtE population reflected a population at high risk of stroke and bleeding and characteristic of other patients in the representative registries. Patients in the CtE registry had a median CHA₂DS₂-VASc score of 4. Technical success rates (93.6%) and procedural success rates (89%) accorded with published data (despite inconsistent definitions and the early learning curve effect for several UK centres).
- The crude event rate for ischaemic stroke was 2.6 events per 100 person years. The median CHA₂DS₂-VASc score was 4 which in a series of 180,000 patients without oral anticoagulation led to a thromboembolic event rate of 6.7 – 7.8 per 100 patients per year (Friberg et al.2012). This can be compared with the actual CtE achieved incidence of 2.6 thromboembolic events (95% CI 1.3 -4.8) per 100 patients a year. The latter can also be compared with a historical expected adjusted stroke and thromboembolism risk of 9.3% at one year follow up (ESC Guidelines. 2012).
- Hence LAAO within the CtE was associated with a decreased risk of an ischaemic event compared with historical epidemiological data.

- The main reasons for undertaking LAAO were related to a history or risk of severe bleeding. Patients in the CtE registry had a relatively high risk of bleeding as measured by the median HAS BLED score of 4.

6 Criteria for Commissioning

Treatment with LAAO will be routinely funded in the circumstances outlined below:

Eligibility criteria

Inclusion

Patients with non-valvular Atrial Fibrillation with a high thromboembolic risk (CHA₂DS₂-VASc score of 2 or greater) and with physician-assessed contraindications to Oral Anti-Coagulants (both Vitamin K Antagonists and Novel Oral Anti-Coagulants):

1. Patients with a history of severe/major haemorrhage such as intracranial or major gastrointestinal bleeding in whom further oral anticoagulation is likely to lead to a recurrent bleed.
2. Patients with a high risk of bleeding or inherited /acquired bleeding disorder should be discussed on an individual basis with a haematologist.
3. Patients with documented physician assessed contraindications to anticoagulation therapy.
4. Patients with a Rockwood frailty score (CHSA) of <6.
5. Patients with a high stroke risk who have suffered a thromboembolic event/ischaemic stroke despite OAC i.e. failed therapy with a therapeutic International Normalised Ratio (INR) at the time of the event or with evidence of compliance with DOAC medication at the time of the event.

NB: The cut-off of ≥ 2 and not higher has been chosen to be consistent with NICE Guidance CG180 and to prevent patients who have a CHA₂DS₂-VASc score of between 2-3 of remaining unprotected and at risk of stroke if OACs are

contraindicated in their case).

For the consideration of LAAO, it is important that a comprehensive patient screen and risk assessment takes place. Patient selection procedures should take into account the following:

- The CHA₂DS₂-VASc score for estimated annual stroke risk and the HAS-BLED score which estimates annual bleeding risk (A HAS-BLED score ≥ 3 = a high bleeding risk). The CHA₂DS₂-VASc and the HAS-BLED scores complement each other when assessing the patient, as the latter additionally takes into account drugs, alcohol, labile INRs and bleeding whereas the former takes into account congestive heart failure, vascular disease, female sex and diabetes. These risk factors are in addition to age, sex, stroke and hypertension which are common to both scores.
- The HAS-BLED score gives a measure of a given patient's bleeding risk. It is anticipated that most patients who are considered for LAAO will have a HAS-BLED score above 2. The HAS-BLED score will be recorded in any National Registry. Need for anticoagulation per se however is based on the CHA₂DS₂-VASc score of 2 or greater and contraindication to anticoagulation will be the primary driver for considering possible LAAO.
- A HAS-BLED score of ≥ 3 should not be considered by itself to be an indication for LAAO.
- Percutaneous LAAO should be undertaken only in surgical cardiothoracic units. Operators (interventional or electrophysiological) and Echo- cardiographers need relevant training and expertise.
- Centres which are beginning a programme of LAAO, or are using a new device, should have relevant training and proctoring in the technique and the device use. This should include off-site training where provided by a company, and on-site proctoring until the operators are trained.
- Given that the benefit of left atrial appendage occlusion accrues over time, it is not expected that patients with a life expectancy of less than 3 years will be selected for LAAO.

- Frailty score measurements (such as Rockwood, KATZ), assessment of comorbidities, measurement of impaired organ function (renal, kidney) should be undertaken to inform patient selection, which should be based on expected prospective Quality of life and longevity. LAAO should not be used as a salvage therapy but only in circumstances where patients are best able to attain maximum and long term benefit from a reduction in ischaemic strokes and mortality.

Anti-Thrombosis Protocols

Patients undergoing LAAO will be expected to be assessed for single or dual antiplatelet therapy for a minimum of six months following implant, taking into account their individual clinical circumstances/risk profile and manufacturers advice.

Exclusion criteria:

- Life expectancy less than 3 years.
- Left atrial appendage thrombus visualised.
- Valvular atrial fibrillation (i.e rheumatic mitral stenosis, mechanical mitral valve).
- Other indications for long-term or lifelong OAC—mechanical prosthetic valve, pulmonary embolism and deep vein thrombosis, thrombi in the left atrium or ventricle.
- Contraindications for trans-septal catheterisation—left atrial thrombus or tumour, active infection.
- Patients clinically eligible and suitable for oral anticoagulants.
- Low risk for stroke $CHA_2DS_2-VASc < 2$.

7 Patient Pathway

Patients are likely to be referred via specialist services rather than by general practitioners. Patients will have been seen usually by a stroke physician, care of the elderly physician, general medical physician, or cardiologist.

Patients for this therapy will be elective, not urgent or emergent. Referral will be by letter or electronic means to the relevant cardiologist who will see the patient in clinic and discuss the potential risks and benefits of LAAO.

Pre-procedure investigations may include echocardiography or CT, or none.

Patients will be admitted for the procedure on the day, or the day before. The procedure will usually be done under general anaesthesia with echocardiographic control.

Patients will need an echocardiogram before discharge, to ensure that there is no significant pericardial effusion, or device embolization. Patients are usually discharged the next day, on an appropriate anti-thrombotic regimen treatment for up to six months to cover the period of endothelialisation of the device.

8 Governance Arrangements

Treatment will be commissioned from a limited number of centres and each centre will be expected to demonstrate minimum numbers of procedures. It is anticipated that sites will produce information leaflets (clinical indications, clinical benefits, complications, need for follow up, current evidence base and its limitations) for patients about left atrial appendage occlusion. Alternatively implanting sites will have information available via website.

Subsequent to the acute period (0-7days), follow-up will likely be in the centre which undertook the procedure. It is anticipated that patients will be seen at least once thereafter. Annual monitoring by the main treatment centre will take place until the RCTs report in 2023 and the policy is reviewed.

A National Registry will be set up to record procedural outcomes with left atrial appendage occlusion. Definitions for clinical and safety outcomes will need to be agreed and standardised with other registries to ensure comparability of outcome data. Submission of data to this database will be mandatory for all procedures undertaken. Linkage with other databases for follow-up and with the Medical Research Information Service is encouraged. The National Registry will draw on the data-fields already present during the Commissioning through Evaluation

programme, and will standardise these. Funding for a National Registry should be agreed for clinical and research governance assurance by the key stakeholders across the NHS and professional groups.

The use of LAAO will be subject to the NHS England clinical decision support system.

A suspected problem ('adverse incident') with the medical device should be reported using the Yellow Card Scheme as soon as possible at the following link:

<https://www.gov.uk/report-problem-medicine-medical-device>

9 Mechanism for Funding

The device is excluded from the national tariff and will be funded by pass through payments made against invoices raised by provider trusts or through the high costs device programme.

The procedure is included in tariff and will be funded through the routine contract procedures. A specific code for LAAO (K62.5 Percutaneous transluminal occlusion of left atrial appendage) was introduced in August 2013 and maps to HRG EA11.

10 Audit Requirements

Centres should undertake an annual audit of their LAAO programme, reporting efficacy and safety outcomes within the clinical governance structure of their hospital and network. They should benchmark themselves against existing and developing regional, national and international data. Audits should cover referral, patient selection, procedure indications, method of anaesthesia, duration of hospital stay, number of devices per patient, and peri-procedural complications. Complications (including time of occurrence) to be monitored would include strokes/TIAs/embolic events, bleeding, device embolization, air –embolism, pericardial effusion +/- cardiac tamponade +/-pericardiocentesis, all cause/ cardiovascular, procedure- related deaths.

11 Documents which have informed this Policy

This document updates and replaces Clinical Commissioning Policy Statement: Left Atrial Appendage (LAA) Occlusion April 2013 Reference: NHSCB/A09/PS/c. LAAO is not routinely commissioned for all other indications.

See References.

12 Date of Review

This document will be reviewed when information is received which indicates that the policy requires revision.

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