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MEDICAL POLICY – 7.01.172

Surgical Left Atrial Appendage Occlusion Devices for Stroke Prevention in Atrial Fibrillation

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Replaces:	N/A	

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POLICY CRITERIA | CODING | EVIDENCE REVIEW | REFERENCES | HISTORY

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Introduction

Atrial fibrillation (AF) is an irregular heartbeat that starts in the upper chambers of the heart (the atria). Because blood isn't pumping the way it should be, blood tends to pool in these two upper chambers. The pooling blood increases the risk of blood clots in the area of the heart called the left atrial appendage. If a blood clot comes loose, it may travel to the brain and cause a stroke. The most common way to keep this from happening is to use medications called blood thinners. Another way to stop blood clots from leaving this area of the heart is by placing a device that permanently closes the opening to the left atrial appendage. This surgical method can be done on its own. It can also be done during open or minimally invasive heart surgery. The use of surgical left atrial appendage occlusion devices is unproven (investigational). More studies are needed to see if this type of treatment improves health outcomes.

Note: The Introduction section is for your general knowledge and is not to be taken as policy coverage criteria. The rest of the policy uses specific words and concepts familiar to medical professionals. It is intended for providers. A provider can be a person, such as a doctor, nurse, psychologist, or dentist. A provider also can be a place where medical care is given, like a hospital, clinic, or lab. This policy informs them about when a service may be covered.

Policy Coverage Criteria

Device	Investigational
Surgical left atrial appendage occlusion devices	**The use of surgical left atrial appendage occlusion devices, including the AtriClip device, for stroke prevention in individuals with atrial fibrillation undergoing open or thoracoscopic cardiac procedures is considered investigational.** **The use of surgical left atrial appendage occlusion devices, including the AtriClip device, for stroke prevention as a stand-alone procedure for stroke prevention in individuals with atrial fibrillation is considered investigational.**

Note: The following codes are not specific to occlusion devices such as the AtriClip. Other methods of exclusion of left atrial appendage described in the codes below are not addressed in this policy. This policy only addresses the use of the AtriClip occlusion device.

Coding

Code	Description
CPT	
33267	Exclusion of left atrial appendage, open, any method (e.g., excision, isolation via stapling, oversewing, ligation, plication, clip)
33268	Exclusion of left atrial appendage, open, performed at the time of other sternotomy or thoracotomy procedure(s), any method (e.g., excision, isolation via stapling, oversewing, ligation, plication, clip) (List separately in addition to code for primary procedure)
33269	Exclusion of left atrial appendage, thoracoscopic, any method (e.g., excision, isolation via stapling, oversewing, ligation, plication, clip)

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Evidence Review

Description

Atrial fibrillation (AF) is the most common type of cardiac arrhythmia. Stroke associated with AF is primarily embolic, tends to be more severe than the typical ischemic stroke, and causes higher rates of mortality and disability. As a result, stroke prevention is one of the main goals of AF treatment. Treatment with anticoagulant medications is a first-line approach to stroke prevention in individuals with AF, although occlusion of the left atrial appendage (LAA) may offer a non-pharmacological alternative to anticoagulant medications for those with a contraindication or intolerance to long-term anticoagulant use or with poor anticoagulant adherence. Multiple surgical techniques may be used to excise or occlude the LAA. One device, the AtriClip Left Atrial Appendage Exclusion System, has approval from the United States (US) Food and Drug Administration (FDA) for surgical LAA occlusion for stroke prevention in individuals with AF.

Background

Atrial Fibrillation

Nonvalvular AF is the most common type of cardiac arrhythmia, affecting at least 2.7 million people in the US. The risk of AF has been found to be lower in Black, Hispanic, and Asian individuals relative to White individuals, following adjustment for demographic and AF risk factors.[1,2] AF is typically described according to frequency and duration and includes paroxysmal (duration up to one week), persistent (>one week), long-term persistent (>one year), or permanent (normal sinus rhythm cannot be restored despite treatment).[3] Stroke is the most serious complication of AF. The estimated incidence of stroke in non-treated individuals with AF is 5% per year. Despite a lower risk of AF, Black and Hispanic individuals have an increased risk of stroke compared with White individuals.[4,5] Although this paradox may be partially attributable to clinical factors (e.g., congestive heart failure, hypertension, type 2 diabetes), Black and Hispanic individuals with AF are less likely than White individuals to receive stroke prevention therapy.[6] Stroke associated with AF is primarily thromboembolic, tends to be more severe than the typical ischemic stroke, and causes higher rates of mortality and disability. As a result, stroke prevention is one of the main goals of AF treatment.

Stroke Prevention

The risk for stroke among individuals with AF is evaluated using several factors. Two commonly used scores, the $CHADS_2$ score and the CHA_2DS_2-VASc score are described in **Table 1**.

Table 1. $CHADS_2$ and CHA_2DS_2-VASc Scores to Predict Ischemic Stroke Risk in Patients With Atrial Fibrillation

Letter	Clinical Characteristics	Points Awarded
C	Congestive heart failure (signs/symptoms of heart failure confirmed with objective evidence of cardiac dysfunction)	1
H	Hypertension (resting blood pressure >140/90 mmHg on at least 2 occasions or current antihypertensive pharmacologic treatment)	1
A	Age ≥75 y	1 ($CHADS_2$) 2 (CHA_2DS_2-VASc)
D	Diabetes (fasting glucose >125 mg/dL or treatment with oral hypoglycemic agent and/or insulin)	1
S	Stroke or transient ischemic attack (includes any history of cerebral ischemia)	2
V	Vascular disease (prior myocardial infarction, peripheral arterial disease, or aortic plaque)	1
A	Age 65-74 y	1
Sc	Sex category of female (female sex confers higher risk)	1

Adapted from Lip et al (2018)[7] and January et all (2014) [8]

Stroke in AF occurs primarily as a result of thromboemboli from the left atrium. The erratic atrial contractions in AF lead to blood stasis in the left atrium, and this low flow state increases the risk for thrombosis. The first-line treatment for stroke prevention in AF is long-term anticoagulation, which has proven efficacy.[9] Warfarin, a vitamin K antagonist, is the predominant agent in clinical use. Several newer direct oral anticoagulant (DOAC) agents, including dabigatran, rivaroxaban apixaban, and edoxaban, have received FDA approval for stroke prevention in nonvalvular AF and have demonstrated noninferiority to warfarin in clinical trials. Warfarin requires frequent monitoring and adjustments as well as lifestyle changes; DOACs do not require the frequent monitoring seen with warfarin therapy. While anticoagulation is effective for stroke prevention, it carries an increased risk of bleeding. Reversal agents can be used to counter the effects of life-

threatening bleeding in individuals using warfarin or DOAC therapy. Such agents carry their own risk of inducing life-threatening thrombosis. For individuals with AF who have a contraindication to warfarin and DOACs, dual antiplatelet therapy with aspirin and clopidogrel is an option for stroke prevention, though it is less protective than either warfarin or DOACs.

The area of the left atrium with the lowest blood flow in AF, and therefore the highest risk of thrombosis, is the LAA. The LAA is a small extension of the left atrium that can vary widely in both size and shape (morphology). LAA morphologies are described according to their appearance and include: the chicken wing, which is the most common morphology and features a prominent bend in the dominant lobe; the cactus, characterized by a dominant central lobe with superior and inferior secondary lobes; the windsock, which features one dominant lobe; and the cauliflower, which is the least common morphology and features numerous lobes with none being dominant. It has been estimated that over 90% of left atrial thrombi occur in the LAA. Surgical removal or exclusion of the LAA is often performed in individuals with AF who are undergoing open heart surgery. Surgical techniques to exclude the LAA include resection or occlusion through stapling or clipping.[9,10]

Percutaneous LAA occlusion is discussed in a separate policy. (See **Related Policies)**.

Summary of Evidence

For individuals with AF at increased risk for embolic stroke undergoing LAA occlusion with an AtriClip device concomitant with open or thoracoscopic cardiac surgical procedures, the evidence includes a randomized controlled trial (RCT), a controlled observational study, and case series. Relevant outcomes are ischemic stroke, cardiac events, and mortality. Although evidence from several systematic reviews and a large (N>10,000) observational study found surgical LAA occlusion was associated with a reduction in the risk of stroke without an increase in the risk of adverse events, direct evidence specifically comparing the AtriClip Left Atrial Appendage Exclusion System with anticoagulation, another surgical occlusion method, or no occlusion is limited. LAA occlusion was associated with a reduced risk of stroke versus no occlusion in the LAAOS III trial, but the trial was not designed to specifically assess the net health benefit of LAA occlusion with an AtriClip device. A retrospective database study that compared the AtriClip device with no occlusion found that AtriClip placement was associated with a lower risk of ischemic stroke, which was not statistically significant, and a reduced risk of thromboembolism that was of marginal statistical significance. The ATLAS RCT reported numerically fewer thromboembolic events through 12 months with AtriClip versus no occlusion and low device-related complications, but noted no significant differences in stroke or mortality. Large (N>100) case series of AtriClip device use with 2- to 3- years follow-up reported stroke rates ≤1% in the

postoperative period and ≤2% in the long-term follow-up. Well-designed RCTs with follow-up of one year or more comparing the AtriClip device with anticoagulation, other surgical occlusion methods, and/or no occlusion are needed to provide adequate evidence for assessment of net health benefit. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals with AF at increased risk for embolic stroke undergoing LAA occlusion with an AtriClip device as a stand-alone procedure, the evidence includes a controlled observational study and case series. Relevant outcomes are ischemic stroke, cardiac events, and mortality. One small (N=40) industry sponsored retrospective observational study reported that use of the AtriClip device as a stand-alone procedure resulted in similar outcomes compared to percutaneous LAA occlusion. This evidence is too limited to draw definitive conclusions. Well-designed RCTs with follow-up of one year or more comparing stand-alone AtriClip device placement with percutaneous LAA occlusion are needed to provide adequate evidence for assessment of net health benefit. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

Ongoing and Unpublished Clinical Trials

Some currently ongoing and unpublished trials that might influence this review are listed in **Table 2**.

Table 2. Summary of Key Trials

NCT. No	Trial Name	Planned Enrollment	Completion Date
Ongoing			
NCT05101993	VClip Post-Market Study	156	Aug 2023 (active, not recruiting)
NCT05144958	Stand-Alone Left Atrial Appendage Occlusion for throMboembolism Prevention in Nonvalvular Atrial fibrillatioN DiseasE Registry (SALAMANDER)	400	Mar 2025 (unknown status)
NCT03838341	Stand-Alone Thoracoscopic Epicardial Left Atrial Appendage Occlusion With AtriClip Device for Thromboembolism Prevention in Nonvalvular Atrial Fibrillation - the Polish Nationwide Registry.	100	Jan 2025 (unknown status)

NCT. No	Trial Name	Planned Enrollment	Completion Date
NCT05723536	PLAI-AF Trial: Hybrid Endo-epicardial Partial Left Atrial Isolation vs. Endocardial Ablation in Patients With Persistent Atrial Fibrillation (PLAI-AF)	80	Dec 2025
NCT05478304	Left Atrial Appendage Exclusion for Prophylactic Stroke Reduction Trial	6500	Apr 2032

NCT: national clinical trial.

[a] Denotes industry-sponsored or cosponsored trial.

Practice Guidelines and Position Statements

The purpose of the following information is to provide reference material. Inclusion does not imply endorsement or alignment with the policy conclusions.

Guidelines or position statements will be considered for inclusion if they were issued by, or jointly by, a US professional society, an international society with US representation, or National Institute for Health and Care Excellence. Priority will be given to guidelines that are informed by a systematic review, include strength of evidence ratings, and include a description of management of conflict of interest.

American Heart Association et al

In 2023, the American Heart Association, in conjunction with the American College of Cardiology, the American College of Clinical Pharmacy, and the Heart Rhythm Society, issued a joint guideline on the management of individuals with atrial fibrillation (AF).[40] The following are the recommendations provided on performing LAAC for patients undergoing cardiac surgery:

- In patients with AF undergoing cardiac surgery with a CHA_2DS_2-VASc score ≥2 or equivalent stroke risk, surgical LAA exclusion, in addition to continued anti-coagulation, is indicated to reduce the risk of stroke and systemic embolism. (Class of recommendation I: Level of evidence: A)
- In patients with AF undergoing cardiac surgery and LAA exclusion, a surgical technique resulting in the absence of flow across the suture line and a stump of <1 cm as determined by intraoperative trans-esophageal echocardiography should be used. (Class of recommendation I: Level of evidence: A)

- In patients with AF undergoing cardiac surgery with CHA_2DS_2-VASc score ≥2 or equivalent stroke risk, the benefit of surgical LAA exclusion in the absence of continued anticoagulation to reduce the risk of stroke and systemic embolism is uncertain. (Class of recommendation IIb: Level of evidence: A)

No recommendation was made regarding the method of surgical LAA occlusion.

European Heart Rhythm Association & Heart Rhythm Society et al

In 2024, the European Heart Rhythm Association, in conjunction with the Heart Rhythm Society, the Asia Pacific Heart Rhythm Society, and Latin American Heart Rhythm Society, issued a joint expert consensus statement on surgical or catheter ablation of individuals with AF.[41] The following are the recommendations provided on performing LAA exclusion for patients undergoing surgical or hybrid AF ablation:

- Exclusion of the left atrial appendage is beneficial as a part of surgical AF ablation procedures (stand-alone or concomitant). (Category of advice: TO DO, based on randomized trials)

Society for Cardiovascular Angiography & Interventions et al

In 2023, the Society for Cardiovascular Angiography & Interventions and Heart Rhythm Society issued a consensus statement on transcatheter endovascular left atrial appendage closure (LAAC).[42] The following are the recommendations on patient selection and physician experience prior to receiving or performing LAAC:

- Transcatheter LAAC is appropriate for patients with nonvalvular atrial fibrillation with high thromboembolic risk who are not suited for long-term oral anticoagulation and who have adequate life expectancy (minimum >one year) and quality of life to benefit from LAAC. There should be patient-provider discussion for shared decision making.
- Physicians performing LAAC should have a prior experience, including 50 or more prior left-sided ablations or structural procedures and 25 or more transseptal punctures (TSPs). Interventional imaging physicians should have experience in guiding 25 or more TSPs before supporting any LAAC procedures independently.

No recommendation was made regarding the method of surgical LAA occlusion.

Society for Thoracic Surgeons

In 2023, the Society for Thoracic Surgeons (STS) published guidelines for the surgical treatment of atrial fibrillation.[43] The following are the recommendations on patient selection and physician experience prior to receiving or performing LAAC:

- Left atrial appendage obliteration for atrial fibrillation is recommended for all first-time nonemergent cardiac surgery procedures, with or without concomitant surgical ablation, to reduce morbidity from thromboembolic complications.
- Isolated surgical left atrial appendage obliteration may be considered in patients with longstanding persistent atrial fibrillation, a high stroke risk, and contraindications for or failure of long-term oral anticoagulation. (Class of recommendation IIb: Level of evidence: B)

No recommendation was made regarding the method of surgical LAA occlusion.

American College of Chest Physicians

Guidance from the American College of Chest Physicians in 2018[7] recommends:

- In patients with AF at high risk of ischemic stroke who have absolute contraindications for oral anticoagulants (OAC), we suggest using LAA occlusion (weak recommendation, low quality evidence).
- In AF patients at risk of ischemic stroke undergoing cardiac surgery, we suggest considering surgical exclusion of the LAA for stroke prevention, but the need for long-term OAC is unchanged (weak recommendation, low quality evidence).

Neither statement recommends a specific occlusion method or approach.

Medicare National Coverage

There is no national coverage determination.

Regulatory Status

In June 2010, the AtriClip LAA Exclusion System (Atricure) was cleared for marketing by the US Food and Drug Administration (FDA) through the 510(k) process (K093679). The FDA determined that this device was substantially equivalent to existing devices for occlusion of the LAA. The AtriClip has gone through numerous iterations since 2010, primarily relating to changes in the clip material composition and refinements of the clip applicator. The current FDA cleared indication is unchanged from the original 2010 indication, which states that the AtriClip is indicated for "exclusion of the LAA, performed under direct visualization, in conjunction with other cardiac surgical procedures."[11] The FDA clearance documentation notes that direct visualization "requires that the surgeon is able to see the heart directly, with or without assistance from a camera, endoscope, etc. or other appropriate viewing technologies." As of 2025, AtriCure markets six different versions of the AtriClip device, whose use varies according to LAA size and type of concomitant surgical procedure.[12]

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History

Date	Comments
11/01/22	New policy, approved October 11, 2022. Policy created with a literature update performed through June 15, 2022. The use of surgical left atrial appendage occlusion devices, including the AtriClip device, for stroke prevention in individuals with atrial fibrillation undergoing open or thoracoscopic cardiac procedures is considered investigational. The use of surgical left atrial appendage occlusion devices, including the AtriClip device, for stroke prevention as a stand-alone procedure for stroke prevention in individuals with atrial fibrillation is considered investigational.

Date	Comments
11/01/23	Annual Review, approved October 9, 2023. Policy updated with literature review through June 17, 2023; references added. Policy statements unchanged. Changed the wording from "patient" to "individual" throughout the policy for standardization.
11/01/24	Annual Review, approved October 7, 2024. Policy updated with literature review through June 14, 2024; references added. Policy statements unchanged.
04/01/25	Interim Review, approved March 10, 2025. Added note to Coding table for clarification explaining the codes are not specific to occlusion devices such as AtriClip. However, the policy is specific and only addresses occlusion devices. Other methods of exclusion of left atrial appendage are not addressed in the policy.
11/01/25	Annual Review, approved October 27, 2025. Policy updated with literature review through June 16, 2025; references added. Policy statements unchanged.

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