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

Policy # 00806
Original Effective Date: 05/01/2023
Current Effective Date: 03/10/2025

Applies to all products administered or underwritten by Blue Cross and Blue Shield of Louisiana and its subsidiary, HMO Louisiana, Inc. (collectively referred to as the "Company"), unless otherwise provided in the applicable contract. Medical technology is constantly evolving, and we reserve the right to review and update Medical Policy periodically.

Note: Percutaneous Left-Atrial Appendage Closure Devices for Stroke Prevention in Atrial Fibrillation is addressed separately in medical policy 00296.

Services Are Considered Investigational

Coverage is not available for investigational medical treatments or procedures, drugs, devices or biological products.

Based on review of available data, the Company considers 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 to be **investigational.***

Based on review of available data, the Company considers 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 to be **investigational.***

Background/Overview

Atrial Fibrillation

Nonvalvular atrial fibrillation (AF) is the most common type of cardiac arrhythmia, affecting at least 2.7 million people in the United States. The risk of AF has been found to be lower in Black, Hispanic, and Asian patients relative to White patients, following adjustment for demographic and AF risk factors. AF is typically described according to frequency and duration and includes paroxysmal (duration up to 1 week), persistent (>1 week), long-term persistent (>1 year), or permanent (normal sinus rhythm cannot be restored despite treatment). Stroke is the most serious complication of AF. The estimated incidence of stroke in non-treated patients with AF is 5% per year. Despite a lower risk of AF, Black and Hispanic patients have an increased risk of stroke compared with White patients. Although this paradox may be partially attributable to clinical factors (e.g., congestive heart failure, hypertension, type 2 diabetes), Black and Hispanic patients with AF are less likely than White patients to receive stroke prevention therapy. 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 patients 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) and January et al (2014)

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. 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 U.S. Food and Drug Administration (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 left atrial appendage (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 patients with AF who are undergoing open heart surgery. Surgical techniques to exclude the LAA include resection or occlusion through stapling or clipping.

FDA or Other Governmental Regulatory Approval

U.S. Food and Drug Administration (FDA)

In June 2010, the AtriClip LAA Exclusion System (Atricure) was cleared for marketing by the U.S. 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." 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 2022, AtriCure markets 7 different versions of the AtriClip device, whose use varies according to LAA size and type of concomitant surgical procedure.

Rationale/Source

This medical policy was developed through consideration of peer-reviewed medical literature generally recognized by the relevant medical community, U.S. Food and Drug Administration approval status, nationally accepted standards of medical practice and accepted standards of medical practice in this community, technology evaluation centers, reference to regulations, other plan medical policies, and accredited national guidelines.

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 U.S. Food and Drug Administration for surgical LAA occlusion for stroke prevention in patients with AF.

Summary of Evidence

For individuals with atrial fibrillation (AF) at increased risk for embolic stroke undergoing left atrial appendage (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 Left Atrial Appendage Occlusion Study (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. Large (N>100) case series of AtriClip device use with 2- to 3-year follow-up reported stroke rates of 1% or fewer in the postoperative period and 2% or fewer in the long-term follow-up. Well-designed RCTs with follow-up of 1 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 1 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.

Supplemental Information

Practice Guidelines and Position Statements

Guidelines or position statements will be considered for inclusion in 'Supplemental Information' 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 (NICE). 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). 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.

Society for Cardiovascular Angiography & Interventions et al

In 2023, the Society for Cardiovascular Angiography & Interventions (SCAI) and Heart Rhythm Society (HRS) issued a consensus statement on transcatheter endovascular left atrial appendage closure (LAAC). 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 >1 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. 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 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).

No guideline statement recommends a specific occlusion method or approach.

U.S. Preventive Services Task Force Recommendations
No U.S. Preventive Services Task Force (USPSTF) recommendations for surgical LAA occlusion have been identified.

Medicare National Coverage
There is no national coverage determination. In the absence of a national coverage determination, coverage decisions are left to the discretion of local Medicare carriers.

Ongoing and Unpublished Clinical Trials
Some currently 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
NCT05144958	Stand-Alone Left Atrial Appendage Occlusion for throMboembolism Prevention in Nonvalvular Atrial fibrillatioN DiseasE Registry (SALAMANDER)	400	Mar 2025
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
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.

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Policy History

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02/02/2023	Medical Policy Committee review
02/08/2023	Medical Policy Implementation Committee approval. New policy.
02/01/2024	Medical Policy Committee review
02/14/2024	Medical Policy Implementation Committee approval. No change to coverage.
02/06/2025	Medical Policy Committee review
02/12/2025	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.

Next Scheduled Review Date: 02/2026

Coding

The five character codes included in the Louisiana Blue Medical Policy Coverage Guidelines are obtained from Current Procedural Terminology (CPT®)‡, copyright 2024 by the American Medical Association (AMA). CPT is developed by the AMA as a listing of descriptive terms and five character identifying codes and modifiers for reporting medical services and procedures performed by physician.

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Codes used to identify services associated with this policy may include (but may not be limited to) the following:

Code Type	Code
CPT	33267, 33268, 33269
HCPCS	NA
ICD-10 Diagnosis	All related Diagnoses

*Investigational – A medical treatment, procedure, drug, device, or biological product is Investigational if the effectiveness has not been clearly tested and it has not been incorporated into standard medical practice. Any determination we make that a medical treatment, procedure, drug, device, or biological product is Investigational will be based on a consideration of the following:

A. Whether the medical treatment, procedure, drug, device, or biological product can be lawfully marketed without approval of the U.S. Food and Drug Administration (FDA) and whether such approval has been granted at the time the medical treatment, procedure, drug, device, or biological product is sought to be furnished; or
B. Whether the medical treatment, procedure, drug, device, or biological product requires further studies or clinical trials to determine its maximum tolerated dose, toxicity, safety, effectiveness, or effectiveness as compared with the standard means of treatment or diagnosis, must improve health outcomes, according to the consensus of opinion among experts as shown by reliable evidence, including:
    1. Consultation with technology evaluation center(s);
    2. Credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community; or
    3. Reference to federal regulations.

NOTICE: If the Patient's health insurance contract contains language that differs from the BCBSLA Medical Policy definition noted above, the definition in the health insurance contract will be relied upon for specific coverage determinations.

NOTICE: Medical Policies are scientific based opinions, provided solely for coverage and informational purposes. Medical Policies should not be construed to suggest that the Company recommends, advocates, requires, encourages, or discourages any particular treatment, procedure, or service, or any particular course of treatment, procedure, or service.

NOTICE: Federal and State law, as well as contract language, including definitions and specific contract provisions/exclusions, take precedence over Medical Policy and must be considered first in determining eligibility for coverage.