LOUISIANA BLUE

Percutaneous Left-Atrial Appendage Closure Devices for Stroke Prevention in Atrial Fibrillation

Policy # 00296
Original Effective Date: 05/18/2011
Current Effective Date: 08/01/2026

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.

Investigational or experimental services are not covered. This includes any drug, device, procedure, or service provided under the investigational arm of a clinical trial or clinical study. These services are excluded from coverage under benefits.

Note: Open and Thoracoscopic Approaches to Treat Atrial Fibrillation and Atrial Flutter (Maze and Related Procedures) is addressed separately in medical policy 00624.

Note: Catheter Ablation as Treatment for Atrial Fibrillation is addressed separately in medical policy 00267.

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 devices for percutaneous left atrial appendage closure (e.g., Watchman, Amplatzer Amulet, Lariat®‡, Amplatzer Cardiac Plug)™‡ for the prevention of stroke in individuals with atrial fibrillation (AF) to be **investigational.***

Background/Overview

Atrial Fibrillation and Stroke

Atrial fibrillation (AF) is the most common type of irregular heartbeat, affecting at least 2.7 million people in the U.S. Risk of AF has been found to be lower in Black, Hispanic and Asian patients relative to White patients, including following adjustment for demographic and AF risk factors. Stroke is the most serious complication of AF. The estimated incidence of stroke in nontreated 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. 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 a main goal of AF treatment.

Stroke in AF occurs primarily as a result of thromboembolism from the left atrium. The lack of atrial contractions in AF leads to blood stasis in the left atrium, and this low flow state increases the risk for thrombosis. 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). It has been estimated that 90% of left atrial thrombi occur in the LAA.

Treatment
Pharmacologic
The main treatment for stroke prevention in AF is anticoagulation, which has proven efficacy. 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 below in Table 1. Warfarin or newer anticoagulant medications, including dabigatran, rivaroxaban, apixaban, and edoxaban are options for stroke prevention. In nonvalvular AF, newer anticoagulants have demonstrated noninferiority to warfarin in clinical trials. While anticoagulation is effective for stroke prevention, it carries an increased risk of bleeding. Also, warfarin requires frequent monitoring and adjustments as well as lifestyle changes. Newer agents do not require the frequent monitoring seen with warfarin therapy. The 2018 American College of Chest Physicians guidelines (updated from 2012) recommend that CHA_2DS_2VASc be used to evaluate stroke risk, and patients initially identified as having a low stroke risk should not be given antithrombotic therapy. In addition, they recommend bleeding risk assessments be given to every patient at every patient contact and that "potentially modifiable bleeding risk factors" should be the initial focus.

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).

Bleeding is the primary risk associated with systemic anticoagulation. Risk scores have been developed to estimate the risk of significant bleeding in patients treated with systemic anticoagulation, such as the HAS-BLED score, which has been validated to assess the annual risk of significant bleeding in patients with AF treated with warfarin. The score ranges from 0 to 9, based on clinical characteristics, including the presence of hypertension, renal and liver function, history of stroke, bleeding, labile international normalized ratios, age, and drug/alcohol use. Scores of 3 or greater are considered to be associated with a high risk of bleeding, potentially signaling the need for closer monitoring of patients for adverse risks, closer monitoring of international normalized ratios, or differential dose selections of oral anticoagulants or aspirin.

Surgery
Surgical removal, or exclusion, of the LAA is often performed in patients with AF who are undergoing open heart surgery for other reasons. Percutaneous left atrial appendage closure (LAAC) devices have been developed as a nonpharmacologic alternative to anticoagulation for stroke prevention in AF. The devices may prevent stroke by occluding the LAA, thus preventing thrombus formation.

Several versions of LAA occlusion devices have been developed. The PLAATO system (ev3 Endovascular) was the first device to be approved by the FDA for LAA occlusion. The device was discontinued in 2007 for commercial reasons, and intellectual property was sold to manufacturers of the Watchman system. The Watchman Left Atrial Appendage System (Boston Scientific) is a self-expanding nickel titanium device. It has a polyester covering and fixation barbs for attachment to the endocardium. Implantation is performed percutaneously through a catheter delivery system, using venous access and transseptal puncture to enter the left atrium. Transesophageal echocardiography and fluoroscopy are used to guide the procedure. Following implantation, patients receive anticoagulation with warfarin or alternative agents for approximately 1 to 2 months. After this period, patients are maintained on antiplatelet agents (i.e., aspirin and/or clopidogrel) indefinitely. The Watchman FLX device is a next-generation Watchman device that is also FDA-approved for LAAC. This device is based on the design of the Watchman device, is fully recapturable and repositionable, and was made to occlude a wider size range of LAA than the original Watchman device. The Amplatzer cardiac plug (St. Jude Medical), is FDA-approved for closure of atrial septal defects but not for LAAC. A second-generation device developed for the specific indication of LAAC, the Amplatzer Amulet (Abbott), received FDA approval in August 2021. The Amplatzer Amulet consists of a nitinol mesh disc to seal the ostium of the LAA and a nitinol mesh distal lobe, to be positioned within the LAA. The device is preloaded within a delivery sheath. The Percutaneous LAA Transcatheter Occlusion device (ev3) has also been evaluated in research studies but has not received FDA approval.

The Lariat Loop Applicator is a suture delivery device approved by the FDA, intended to close a variety of surgical wounds. It is not specifically approved for LAAC. While the Watchman and other devices are implanted in the endocardium, the Lariat is a non-implant epicardial device.

Thrombogenesis in patients with AF may not be limited to the left atrium (LA) and up to 10 % of LA thrombi are not located in the LAA, therefore occluding the LAA may not completely eliminate the risk of embolism and stroke. If LAAO incompletely closes the LAA, there is residual communication between the LAA and left atrium, which is referred to as a residual leak. A large residual leak (defined as ≥5 mm) is believed to predispose to thrombus formation.

In September 2021, the FDA sent a letter to healthcare providers indicating that women undergoing percutaneous LAA closure may be at higher risk of adverse procedural outcomes than men. This was based on an analysis of registry data from 49,357 patients who underwent LAA closure with the Watchman device. When adjusted for multiple confounding factors, the study found women were more likely than men to experience any adverse event, major adverse events, and major bleeding. Women also had a significantly higher risk of death (adjusted odds ratio [OR], 2.01; 95% confidence interval [CI], 1.31 to 3.09) but absolute risk was low for both women and men (0.3% vs. 0.1%). In their letter, the FDA stated that they believe the benefits continue to outweigh the risks for approved LAA closure devices when used in accordance with their instructions for use.

Outcome Measures
The optimal study design for evaluating the efficacy of percutaneous LAAC for the prevention of stroke in AF is a randomized controlled trial (RCT) that includes clinically relevant measures of health outcomes. The rate of ischemic stroke during follow-up is the primary outcome of interest, along with rates of systemic embolization, cardiac events, bleeding complications, and death. For the LAAC devices, the appropriate comparison group could be oral anticoagulation, no therapy (for patients who have a prohibitive risk for oral anticoagulation), or open surgical repair.

Ideally, percutaneous LAAC devices would represent an alternative to oral anticoagulation for the prevention of stroke in patients with AF. However, during the post implantation period the LAAC device may be associated with increased thrombogenicity, therefore, anticoagulation is used during the periprocedural period. Patients who cannot tolerate even short-term antithrombotic therapy (anticoagulation therapy or dual antiplatelet therapy [aspirin plus a $P2Y_{12}$ inhibitor such as clopidogrel]) are not ideally suited for LAAO.

TEE is typically done between one and six months post procedure. Device-related thrombus and/or peri device leak ≥5 mm may be indications for continued anticoagulation. If the TEE demonstrates that the LAA is completely occluded and long-term anticoagulation is contraindicated, only aspirin is continued indefinitely. If any leak is present postsurgical LAAO, oral anticoagulation should be continued. Severe complications are rate but include pericardial effusion/tamponade, vascular injury, device erosion or embolization, stroke, cardiac arrest, and death.

Most studies evaluating percutaneous LAAC devices have included patients who are eligible for anticoagulation.

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FDA or Other Governmental Regulatory Approval

U.S. Food and Drug Administration (FDA)

In 2002, the PLAATO system (ev3 Endovascular) was the first device to be approved by the FDA for LAA occlusion. The device was discontinued in 2007 for commercial reasons, and intellectual property was sold to manufacturers of the Watchman system.

In 2015, the Watchman™‡ Left Atrial Appendage Closure Technology (Boston Scientific) was approved by the FDA through the premarket approval process by the Left Atrial Appendage Versus Warfarin Therapy for Prevention of Stroke in Patients with Atrial Fibrillation RCT (PROTECT AF). In 2020, the Watchman FLX device (Boston Scientific) was approved by the FDA based on the single-arm, nonrandomized PINNACLE FLX study.

The Amplatzer™‡ Amulet™‡ Left Atrial Appendage Occluder (Abbott) received FDA approval in 2021 through the premarket approval process based on results from the Amplatzer Amulet Left Atrial Appendage Occluder Randomized Controlled Trial (Amulet IDE Trial). The Watchman and Amplatzer Amulet devices are indicated to reduce the risk of thromboembolism from the LAA in individuals with nonvalvular AF who:

- Are at increased risk for stroke and systemic embolism based on $CHADS_2$ or CHA_2DS_2-VASc scores and are recommended for anticoagulation therapy;
- Are deemed by their physicians to be suitable for anticoagulation therapy; and
- Have an appropriate rationale to seek a nonpharmacologic alternative to anticoagulation therapy, taking into account the safety and effectiveness of the device compared to anticoagulation therapy.

FDA product code: NGV.

Several other devices are being evaluated for LAA occlusion but are not approved in the U.S. for percutaneous LAAC. In 2006, the Lariat™‡ Loop Applicator device (SentreHEART [now AtriCure]), a suture delivery system, was cleared for marketing by the FDA through the 510(k) process. The intended use is to facilitate suture placement and knot tying in surgical applications where soft tissues are being approximated or ligated with a pretied polyester suture. The Amplatzer Cardiac Plug device (St. Jude Medical [now Abbott]) and WaveCrest™‡ (Johnson & Johnson Biosense Webster) have CE approval in Europe for LAAC but are not currently approved in the U.S. for this indication.

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.

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Stroke prevention in patients with atrial fibrillation (AF) is an important goal of treatment. Treatment with anticoagulant medications is the most common approach to stroke prevention. Because most embolic strokes originate from the left atrial appendage, occlusion of the left atrial appendage may offer a nonpharmacologic alternative to anticoagulant medications to lower the risk of stroke. Multiple percutaneously deployed devices are being investigated for left atrial appendage closure (LAAC). Two types of left atrial appendage devices (the Watchman and Amplatzer Amulet devices) have approval from the U.S. Food and Drug Administration (FDA) for stroke prevention in patients with AF.

Summary of Evidence
For individuals who have atrial fibrillation (AF) who are at increased risk for embolic stroke who receive a U.S. Food and Drug Administration (FDA)-approved percutaneous left atrial appendage closure (LAAC) device (e.g., the Watchman or Amulet device), the evidence includes randomized controlled trials (RCTs) and observational studies. Relevant outcomes are overall survival, morbid events, and treatment-related morbidity.

Two initial industry-sponsored RCTs compared the Watchman device with warfarin. The PROTECT AF trial (2009) reported noninferiority of LAAC vs warfarin on a composite outcome of stroke, cardiovascular/unexplained death, or systemic embolism after 2 years of follow-up, with continued benefits with the Watchman device after 4 years of follow-up. FDA concerns were driven by high early procedural complications. The PREVAIL trial (2014) did not demonstrate noninferiority for the same composite outcome but did demonstrate noninferiority of the Watchman device to warfarin for late ischemic stroke and systemic embolization (>7 days post-procedure). FDA approval relied in part on pooled patient-level analyses rather than unequivocal success of individual trials. Patient-level meta-analyses at 5-year follow-up for the 2 Watchman trials reported that the Watchman device is noninferior to warfarin on the composite outcome of stroke, systemic embolism, and cardiovascular death. The Watchman was associated with lower rates of major bleeding, particularly hemorrhagic stroke, and mortality over the long term.

Evidence for the Amplatzer Amulet device comes from 2 RCTs comparing the Amulet and Watchman devices, one of which was a shorter trial that assessed periprocedural outcomes at 45 days and again at 13 months. The second trial comparing the Amulet and Watchman devices found the Amulet device to be noninferior to the Watchman device after 18 months of follow-up for a composite efficacy outcome that included ischemic stroke or systemic embolism and for a composite safety outcome that included all-cause mortality, major bleeding or procedure-related complications. At 3 and 5 year follow-up, clinical outcomes remained similar between patients in the Amulet group and the Watchman group, with a higher percentage of Amulet users not using oral anticoagulation.

PRAGUE-17 RCT evaluated the use of either the Amplatzer Amulet or Watchman device versus anticoagulants; subgroup analyses according to device were not performed. After up to 4 years of follow-up, the study found LAAC with either the Watchman or Amulet was noninferior to anticoagulants for a composite outcome that included stroke, transient ischemic attack (TIA),

systemic embolism, clinically significant bleeding, significant periprocedural or device-related complications, or cardiovascular mortality.

The OPTION trial (2024) was an international randomized trial involving 1600 patients with atrial fibrillation who had an elevated score (≥2 in men and ≥3 in women) on the CHA_2DS_2-VASc scale and who underwent catheter ablation. Patients were randomly assigned in a 1:1 ratio to undergo left atrial appendage closure (N 803) or receive oral anticoagulation (N 797). The primary safety end point, tested for superiority, was non–procedure-related major bleeding or clinically relevant nonmajor bleeding. Procedural bleeding, which is the most common adverse effect of LAAC, was not included in the primary safety endpoint. The primary efficacy end point, tested for noninferiority, was a composite of death from any cause, stroke, or systemic embolism at 36 months. Neither strategy has demonstrated a consistent or reproducible reduction in all-cause mortality in randomized trials; adding an endpoint not affected by either treatment inflates number of events which can make noninferiority easier to reach. Stroke rate was very low in both arms (1.2% and 1.3%); to discern any signal of noninferiority or superiority of the device with very low stroke rate would require much higher number of participants (underpowering). The secondary end point, tested for noninferiority, was major bleeding, including procedure-related bleeding, through 36 months. At 36 months, a primary safety end-point event had occurred in 65 patients (8.5%) in the left atrial appendage closure group (device group) and in 137 patients (18.1%) in the anticoagulation group ($P<0.001$ for superiority); a primary efficacy end-point event had occurred in 41 patients (5.3%) and 44 patients (5.8%), respectively ($P<0.001$ for noninferiority); and a secondary end-point event had occurred in 3.9% and 5.0% ($P<0.001$ for noninferiority). Complications related to the appendage closure device or procedure occurred in 23 patients (3%). One in five patients had incomplete LAA closure with peri device leak.

While earlier warfarin-era trials suggested a potential long-term net clinical benefit of LAAC in select populations, emerging higher-quality randomized evidence in the DOAC (direct oral anticoagulant) era published in 2026 has not consistently demonstrated net health outcome improvement. The CHAMPION-AF trial targeted anticoagulation-eligible AF population and CLOSURE-AF targeted high-bleeding-risk AF population.

The CHAMPION-AF trial (2026) was a large, industry-sponsored, randomized, prospective, international noninferiority trial that compared percutaneous left atrial appendage closure (LAAC) using the Watchman FLX device with non–vitamin K antagonist oral anticoagulant (DOAC) therapy in patients with nonvalvular AF who were *eligible* for long-term anticoagulation. A total of 3,000 patients were randomized 1:1 and followed for a median of 3 years. The study population was moderate risk, with a mean CHA_2DS_2-VASc score of 3.5 and a low mean HAS-BLED score of 1.3. The primary efficacy endpoint was a composite of cardiovascular death, stroke (ischemic or hemorrhagic), or systemic embolism, tested for noninferiority using an absolute noninferiority margin of 4.8 percentage points. At 3 years, the primary endpoint occurred numerically more often in the device group than in the anticoagulation group (5.7% vs 4.8%), meeting the prespecified criterion for noninferiority but not superiority. Stroke events were more frequent in the device group, driven primarily by ischemic stroke (17 more strokes, HR 1.61). The primary safety endpoint, non–

procedure-related bleeding, occurred less frequently in the device group compared with the anticoagulation group (10.9% vs 19.0%), demonstrating superiority for bleeding reduction. In contrast, the secondary safety endpoint of procedural plus non-procedural major bleeding showed numerically similar event rates between groups (83 vs 87 events; 5.9% vs 6.4%) and met criteria for noninferiority but not superiority. Procedure-related complications included pericardial effusion requiring intervention (0.7%), device-related thrombus (4.8%), and peri-device leak (21%). Two strokes were attributed to clinically significant device-related thrombus.

There are several design considerations related to the CHAMPION-AF trial. Event rates in both study arms were substantially lower than anticipated, resulting in a relatively wide noninferiority margin that permits a potentially higher *relative* risk of thromboembolic events in the device group. The trial showed numerically higher ischemic stroke in the device arm (absolute +1.1%) and device-related thrombus (around 5%); noninferiority was demonstrated based on the prespecified statistical margin, despite numerically higher ischemic stroke rates and lower-than-anticipated event rates, limiting conclusions regarding clinical equivalence. Additionally, more than two-thirds of participants had paroxysmal atrial fibrillation, and patients with very high stroke risk (CHA_2DS_2-VASc ≥ 5) were under-represented, limiting generalizability to higher-risk populations. The trial evaluated only one LAAC device and mandated post-implant antithrombotic therapy, which tempers conclusions regarding the ability of LAAC to fully replace anticoagulation in patients otherwise suitable for DOAC therapy.

The CLOSURE-AF trial (2025) was a publicly funded, pragmatic, multicenter randomized controlled trial conducted in Germany that compared catheter-based LAAC using multiple approved devices with physician-directed best medical therapy in patients with atrial fibrillation at high risk of both stroke and bleeding (population that LAAC is most often used for). A total of 888 patients were included in the primary analysis, with a mean age of 77.9 years, a mean CHA_2DS_2-VASc score of 5.2, and a mean HAS-BLED score of 3.0, representing a substantially higher-risk population than that enrolled in CHAMPION-AF.

The primary endpoint was a composite of stroke, systemic embolism, major bleeding, and cardiovascular or unexplained death, tested for noninferiority using a hazard ratio margin of 1.3. After a median follow-up of 3 years, LAAC failed to meet noninferiority criteria compared with medical therapy. Primary endpoint events occurred more frequently in the device group than in the medical-therapy group (16.8 vs 13.3 events per 100 patient-years), and restricted mean survival time favored medical therapy.

No significant reduction in major bleeding was observed with LAAC compared with medical therapy. Bleeding events in the device group were concentrated in the early post-procedural period and were attributed in part to periprocedural complications and post-implant antiplatelet therapy, without evidence of later bleeding reduction compared with medical therapy. Serious adverse events were common in both groups but occurred more frequently in patients undergoing LAAC. Periprocedural complications included pericardial tamponade, device embolization requiring surgical retrieval, and procedure-related mortality. Authors concluded that LAAC was not

noninferior to physician-directed best medical care over a 3-year follow-up period. The editorial in NEJM noted that the findings in this trial should have immediate clinical effect as LAAC failed to fulfill its theoretical promise to become an alternative treatment to best medical therapy for AF population, at least for older patients at high risk of stroke and bleeding; best individualized medical therapy should remain standard treatment.

The CLOSURE-AF findings suggest that, in older population with advanced comorbidity and high bleeding risk, LAAC does not confer an overall clinical advantage compared with contemporary medical therapy and may expose patients to early procedural harm without demonstrable net benefit. The pragmatic nature of the trial, inclusion of multiple devices, and use of real-world medical therapy enhance generalizability to routine clinical practice, particularly for patients similar to those currently targeted for LAAC on the basis of bleeding risk.

Taken together, these trials do not demonstrate consistent improvement in net health outcomes with percutaneous LAAC compared with optimal medical therapy, particularly in populations at highest risk of stroke and bleeding. Long-term comparative effectiveness data and more precise identification of patient subgroups most likely to benefit from LAAC are needed to define its appropriate role compared to optimal medical therapy including oral anticoagulation.

For individuals who have AF who are at increased risk for embolic stroke who receive a percutaneous LAAC device other than the Watchman device or Amplatzer Amulet device (eg, Lariat or Amplatzer Cardiac Plug), the evidence includes one RCT, several nonrandomized comparator studies, and uncontrolled observational studies. Relevant outcomes are overall survival, morbid events, and treatment-related morbidity. One RCT with the Lariat device did not find a reduction in atrial arrhythmias when the device was used in combination with pulmonary vein isolation compared with pulmonary vein isolation alone. One nonrandomized study that compared outcomes among patients undergoing LAAC with the Lariat device with patients receiving anticoagulant or antiplatelet therapy reported fewer thromboembolic events in the group receiving the Lariat device. Evidence from other observational studies of these devices report high procedural success but also numerous complications. In addition, these devices do not have FDA approval for LAAC. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

Supplemental Information

Clinical Input From Physician Specialty Societies and Academic Medical Centers

While the various physician specialty societies and academic medical centers may collaborate with and make recommendations during this process, through the provision of appropriate reviewers, input received does not represent an endorsement or position statement by the physician specialty societies or academic medical centers, unless otherwise noted.

2015 Input
In response to requests, input was received from 1 physician specialty society (2 responses) and 4 academic medical centers, 1 of which provided 4 responses, for a total of 8 responses, while this policy was under review in 2015. Input generally supported the use of a left atrial appendage closure device approved by the U.S. Food and Drug Administration for patients with an increased risk of stroke and systemic embolism, based on $CHADS_2$ or CHA_2DS_2-VASc score. Systemic anticoagulation therapy was recommended, but the long-term risks of systemic anticoagulation outweigh the risks of the device implantation.

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 College of Chest Physicians
In 2018, the American College of Chest Physicians (CHEST) guideline made the following recommendation regarding left atrial appendage (LAA) occlusion and oral anticoagulation: "In patients with AF [atrial fibrillation] at high risk of ischemic stroke who have absolute contraindications for OAC [oral anticoagulation], we suggest using LAA occlusion (Weak recommendation, low-quality evidence)."

American Heart Association
In 2019, the American Heart Association (AHA), in collaboration with the American College of Cardiology (ACC) and the Heart Rhythm Society (HRS), published an update of their guideline for the management of patients with AF. A new recommendation in the guideline states: "Percutaneous LAA occlusion may be considered in patients with AF at increased risk of stroke who have contraindications to long-term anticoagulation." The class of recommendation is IIb (weak) and the level of evidence is B_NR (moderate quality of evidence, nonrandomized). No other LAA closure (LAAC) devices are mentioned in the guideline. Another guideline update was published in 2023. Based on additional data on safety and efficacy of LAA occlusion devices, the class of recommendation was updated to IIa (moderate) compared to the 2019 recommendation of IIb.

The AHA also released a scientific statement in 2021 about managing AF in patients with heart failure and reduced ejection fraction. They state that, "It is reasonable to consider LAA closure in patients with AF and heart failure with reduced ejection fraction (HFrEF) with moderate to high stroke risk and contraindications to long-term oral anticoagulation", however, they also note that the role of LAA therapies in patients with AF with HFrEF needs to be better understood, and this is an opportunity for future research.

Heart Rhythm Society
In collaboration with the Society for Cardiovascular Angiography and Interventions Foundation, the HRS published an expert consensus statement on transcatheter LAAC in 2023. They state that "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."

U.S. Preventive Services Task Force Recommendations
Not applicable.

Medicare National Coverage
Since 2016, the Centers for Medicare & Medicaid Services has a national coverage determination under coverage with evidence development for percutaneous LAAC in AF, as follows:
"LAAC devices are covered when the device has received U.S. Food and Drug Administration (FDA) Premarket Approval (PMA) for that device's FDA-approved indication and meet all of the conditions specified below:

The patient must have:

- A $CHADS_2$ score ≥2 (Congestive heart failure, Hypertension, Age > 75, Diabetes, Stroke/transient ischemia attack/thromboembolism) or CHA_2DS_2-VASc score ≥ 3 (Congestive heart failure, Hypertension, Age ≥ 65, Diabetes, Stroke/transient ischemia attack/thromboembolism, Vascular disease, Sex category).
- A formal shared decision making interaction with an independent non-interventional physician using an evidence-based decision tool on oral anticoagulation in patients with NVAF [nonvalvular atrial fibrillation] prior to LAAC. Additionally, the shared decision making interaction must be documented in the medical record.
- A suitability for short-term warfarin but deemed unable to take long-term oral anticoagulation following the conclusion of shared decision making, as LAAC is only covered as a second line therapy to oral anticoagulants. The patient (preoperatively and postoperatively) is under the care of a cohesive, multidisciplinary team (MDT) of medical professionals. The procedure must be furnished in a hospital with an established structural heart disease (SHD) and/or electrophysiology (EP) program.

The procedure must be performed by an interventional cardiologist(s), electrophysiologist(s), or cardiovascular surgeon(s) that meet the following criteria:

- Has received training prescribed by the manufacturer on the safe and effective use of the device prior to performing LAAC; and,
- Has performed ≥ 25 interventional cardiac procedures that involve transseptal puncture through an intact septum; and,
- Continues to perform ≥ 25 interventional cardiac procedures that involve transseptal puncture through an intact septum, of which at least 12 are LAAC, over a 2-year period."

Patients must be enrolled in approved registries that track outcomes for procedures and devices.

Ongoing and Unpublished Clinical Trials
Some currently ongoing and unpublished trials that might influence this policy are listed in Table 2.

Table 2. Summary of Key Trials

NCT No.	Trial Name	Planned Enrollment	Completion Date
Ongoing			
NCT06686485	Concomitant Left Atrial Appendage Closure and Pulsed Field Ablation-Asia	733	Oct 2029
NCT06465706	A Prospective, Multicenter, Randomized Controlled Trial Assessing the Safety and Efficacy of the LAmbre™‡ Plus Left Atrial Appendage Closure System to REDUCE the Risk of Thromboembolism in Patients With Non-Valvular Atrial Fibrillation	1826	Jan 2030
NCT06861673	Concomitant Pulse Field Ablation Based pulmonary Vein Isolation and left Atrial Appendage Closure - The COCONUT Study	60	Dec 2026
NCT03309332[a]	OSB Lead-AMPLATZER PFO Occluder New Enrollment PAS	1214	Feb 2030
NCT04394546[a]	WATCHMAN FLX Versus NOAC for Embolic Protection in in the Management of Patients With Non-Valvular Atrial Fibrillation	3000	Dec 2027
NCT04226547[a]	Clinical Trial of Atrial Fibrillation Patients Comparing Left Atrial Appendage Occlusion Therapy to Non-vitamin K Antagonist Oral Anticoagulants	2650	Aug 2030
Unpublished			
NCT03463317	Left Atrial Appendage CLOSURE in Patients With Atrial Fibrillation at High Risk of Stroke and Bleeding Compared to Medical Therapy: a Prospective Randomized Clinical Trial	912	Nov 2024
NCT03276169	Left Atrial Function Changes after Left Atrial Appendage Closure in Patients with Persistent Atrial Fibrillation	105	Nov 2020 (updated Mar 2021)

NCT No.	Trial Name	Planned Enrollment	Completion Date
NCT01118299[a]	AMPLATZER Cardiac Plug Clinical Trial	97 (actual; study terminated)	Dec 2018 (updated Apr 2020)
NCT02681042	Left Atrial Appendage Closure with SentreHeart Lariat Device	9	May 2018 (updated Feb 2021)

NCT: national clinical trial.
[a] indicates industry-sponsored study.

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Policy History

Original Effective Date: 05/18/2011
Current Effective Date: 08/01/2026

05/05/2011	Medical Policy Committee review
05/18/2011	Medical Policy Implementation Committee approval. New policy.
05/03/2012	Medical Policy Committee review
05/16/2012	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
05/02/2013	Medical Policy Committee review

Policy # 00296
Original Effective Date: 05/18/2011
Current Effective Date: 08/01/2026

05/22/2013	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
05/01/2014	Medical Policy Committee review
05/21/2014	Medical Policy Implementation Committee approval. Percutaneous added to the title and coverage statement.
06/04/2015	Medical Policy Committee review
06/17/2015	Medical Policy Implementation Committee approval. No change to coverage.
04/07/2016	Medical Policy Committee review
04/20/2016	Medical Policy Implementation Committee approval. An FDA-approved left atrial appendage closure device is considered medically necessary with conditions.
01/01/2017	Coding update: Removing ICD-9 Diagnosis Codes and CPT Coding Update
04/06/2017	Medical Policy Committee review
04/19/2017	Medical Policy Implementation Committee approval. No change to coverage.
06/07/2018	Medical Policy Committee review
06/20/2018	Medical Policy Implementation Committee approval. No change to coverage.
10/04/2018	Medical Policy Committee review
10/17/2018	Medical Policy Implementation Committee approval. Added policy guidelines
10/03/2019	Medical Policy Committee review
10/09/2019	Medical Policy Implementation Committee approval. No change to coverage.
10/01/2020	Medical Policy Committee review
10/07/2020	Medical Policy Implementation Committee approval. Added to policy guideline section.
10/07/2021	Medical Policy Committee review
10/13/2021	Medical Policy Implementation Committee approval. No change to coverage.
08/04/2022	Medical Policy Committee review
08/10/2022	Medical Policy Implementation Committee approval. Policy statements updated to include the FDA-approved Amplatzer Amulet device.
08/03/2023	Medical Policy Committee review
08/09/2023	Medical Policy Implementation Committee approval. No change to coverage.
08/01/2024	Medical Policy Committee review
08/14/2024	Medical Policy Implementation Committee approval. No change to coverage.
08/07/2025	Medical Policy Committee review
08/13/2025	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
05/07/2026	Medical Policy Committee review
05/13/2026	Medical Policy Implementation Committee review.
06/18/2026	Medical Quality Management Committee approval. Coverage changed from eligible for coverage to Investigational. Added “Based on review of available data, the Company considers the use of devices for percutaneous left atrial appendage closure (e.g., Watchman, Amplatzer Amulet, Lariat®‡, Amplatzer Cardiac Plug) ™‡ for the prevention of stroke in individuals with atrial fibrillation (AF) to be investigational.”

Next Scheduled Review Date: 05/2027

Policy # 00296
Original Effective Date: 05/18/2011
Current Effective Date: 08/01/2026

Coding

The five character codes included in the Louisiana Blue Medical Policy Coverage Guidelines are obtained from Current Procedural Terminology (CPT®)‡, copyright 2025 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	33340
HCPCS	No codes
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.

‡ Indicated trademarks are the registered trademarks of their respective owners.

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.

NOTICE: If an authorization for an ongoing course of treatment has been provided to a member and the member changes from one health plan to another health plan (e.g., a member moves from carrier A to Louisiana Blue), Louisiana Blue may honor the previous health plan's authorization for the same service under the same type of in-network benefit for a 90-day transition period. Documentation of the authorization for the ongoing course of treatment from the previous health plan must be provided to us by the member or their provider and the services provided for the course of treatment must otherwise be a covered service under the Louisiana Blue health plan. This provision does not apply to medications covered under the plan's pharmacy benefit.