MEDICAL POLICY

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Medical Policy Title	**Left Atrial Appendage Closure Devices**
Policy Number	**7.01.92**
Current Effective Date	**September 18, 2025**
Next Review Date	**September 2026**

Our medical policies are based on the assessment of evidence based, peer-reviewed literature, and professional guidelines. Eligibility for reimbursement is based upon the benefits set forth in the member's subscriber contract. (Link to Product Disclaimer)

POLICY STATEMENT(S)

I. Percutaneous left atrial appendage (LAA) occlusion (e.g., the WATCHMAN, Amplazter Amulet) devices are considered **medically appropriate** when **ALL** of the following criteria are met:

   A. U.S. Food and Drug Administration (FDA) approved device;

   B. Nonvalvular atrial fibrillation (AF);

   C. Increased risk of stroke and systemic embolism, based on CHA_2DS_2-VASc score greater than or equal to two (2);

   D. Systemic anticoagulation therapy is recommended;

   E. Long-term risks of systemic anticoagulation outweigh the risks of the device implantation. (See Policy Guideline section)

II. Surgical exclusion/excision of the LAA during cardiac surgery is **medically appropriate** when **ALL** of the following criteria are met:

   A. Individual is planning to continue long-term anticoagulation post-surgery;

   B. When goal is to reduce the risk of stroke;

   C. Individual is diagnosed with atrial fibrillation;

   D. Individual has a CHA_2DS_2-VASc score greater than or equal to two (2) or equivalent stroke risk.

III. Percutaneous left atrial appendage closure devices are considered **investigational** when the above criteria are not met.

IV. Surgical LAA exclusion devices, including the AtriClip device, for stroke prevention as a stand-alone procedure, or undergoing a thoracoscopic cardiac procedure in individuals with AF is considered **investigational**.

RELATED POLICIES

Corporate Medical Policy

11.01.03 Experimental or Investigational Services

POLICY GUIDELINE(S)

I. The balance of risks and benefits associated with implantation of a percutaneous LAA occlusion device for stroke prevention, as an alternative to systemic oral anticoagulation, should be determined on an individual basis, through administration of an evidence-based decision tool, taking into account a patient's demonstrated bleeding episodes.

II. The patient's suitability for short-term oral anticoagulation but inability to take long-term oral anticoagulation, must be documented in the medical record and decided by a shared decision-making interaction between the patient and non-implanting physician(s) involved in the patient's care (primary care physician and/or primary cardiologist).

DESCRIPTION

Stroke is the most serious complication of atrial fibrillation (AF). The estimated incidence of stroke in untreated patients with AF is 5% per year. Stroke associated with AF is primarily embolic in nature, 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 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.

CHADS$_2$ or the CHA$_2$DS$_2$-VASc stratification scores

The CHADS$_2$ or the CHA$_2$DS$_2$-VASc are frisk stratification scores used to calculate the risk of stroke in patients with AF. The CHADS$_2$ score assigns points for each of the following findings: congestive heart failure, hypertension, age greater than 75, diabetes, stroke/transient ischemia attack/thromboembolism. The CHA$_2$DS$_2$-VASc assigns points for some of the same findings (congestive heart failure, hypertension, diabetes, stroke/transient ischemia attack/thromboembolism), but with some different or additional criteria: age greater than or equal to 65, vascular disease, gender category.

Anti-Coagulation Treatment

The main treatment for stroke prevention in AF is anticoagulation, which has proven efficacy. Warfarin is the predominant agent in clinical use. A number of newer anticoagulant medications, including dabigatran, rivaroxaban, and apixaban, have received FDA approval for stroke prevention in nonvalvular AF and have demonstrated non-inferiority to warfarin in clinical trials. While anticoagulation is effective for stroke prevention, there is an increased risk of bleeding. Also, warfarin requires frequent monitoring and adjustments, as well as lifestyle changes. Dabigatran does not require monitoring. However, unlike warfarin, the antithrombotic effects of dabigatran are not reversible with any currently available hemostatic drugs.

A number of risk scores have been developed to estimate the risk of significant bleeding in patients treated with systemic anticoagulation. An example is the HAS-BLED score, which assesses the annual risk of significant bleeding in AF patients treated with warfarin. The score ranges from 0 to 9, based on a number of clinical characteristics: hypertension, abnormal renal and/or liver function, stroke,

bleeding, labile international normalized ratios, advanced age (older than 65), drug and/or alcohol use. Scores of 3 or greater are considered to be associated with high risk of bleeding.

Surgical Removal or Exclusion

Surgical removal, or exclusion, of the LAA is often performed in patients with AF who are undergoing open heart surgery for other reasons. Percutaneous LAA closure devices have been developed as a non-pharmacologic alternative to anticoagulation for stroke prevention in AF patients. The devices may prevent stroke by occluding the LAA, thus preventing thrombus formation. Several versions of LAA occlusion devices have been developed.

The WATCHMAN and WATCHMAN FLX left atrial appendage systems (Boston Scientific, Maple Grove, MN) are self-expanding, nickel titanium devices. The devices have a polyester covering and fixation barbs for attachment to the endocardium. Implantation is performed percutaneously through a catheter delivery system, utilizing venous access and transseptal puncture to enter the left atrium. Following implantation, patients are anticoagulated with warfarin or alternate agents for approximately one to two months. After this period, patients are maintained on antiplatelet agents (e.g., aspirin and/or clopidogrel) indefinitely.

The Lariat Loop Applicator is a suture delivery device that is placed around the outside of the LAA and tightened to seal the LAA off from the rest of the heart. This procedure can be done by going through the groin and chest wall. Rather than opening up the chest (open-heart surgery), a long needle is passed under the rib cage to gain access.

The Amplatzer Amulet Left Atrial Appendage Occluder (LAAO) is a second-generation permanent implanted device. It was developed to provide protection against thromboembolic events in high-risk, AF patients by Left Atrial Appendage Closure (LAAC). The device is made of a Nitinol (nickel-titanium) mesh with polyester fabric cover. The Amplatzer Amulet is placed in the patient's left atrial appendage (LAA), the device is intended to prevent blood clots formed in the LAA from entering the bloodstream and potentially causing a stroke.

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. The AtriClip is made of two parallel titanium tubes with elastic nitinol springs covered by knit braided polyester. The delivery allows for application on a beating heart, as well as allows redeployment in case of initial suboptimal placement.

SUPPORTIVE LITERATURE

WATCHMAN Devices

Doshi et al (2023) reported the 2-year results of The PINNACLE FLX trial. The trial evaluated the safety and efficacy of the next-generation WATCHMAN FLX device for left atrial appendage closure in patients with non-valvular atrial fibrillation who were at increased risk of stroke. Conducted across 29 U.S. centers, the study enrolled 395 patients with a mean age of 74 and an average CHA_2DS_2-VASc score of 4.2. At the 2-year mark, the device demonstrated a low rate of ischemic stroke or systemic embolism at 3.4%, which was significantly better than the 8.7% performance goal. Other notable outcomes included a 9.3% rate of all-cause mortality, 5.5% cardiovascular death, 3.4% stroke, and

10.1% major bleeding. There were no additional device-related complications such as embolization or symptomatic thrombi reported after the first year. These final results confirm that the WATCHMAN FLX device offers favorable long-term safety and efficacy for stroke prevention in this high-risk population.

Holmes et al (2014) conducted a second RCT, the PREVAIL trial, it was conducted after the FDA's 2009 decision not to approve the WATCHMAN device to address some of the limitations of the PROTECT AF study, including its inclusion of patients with low stroke risk (CHADS2 scores of 1), high rates of adjunctive antiplatelet therapy use in both groups, and generally poor compliance with warfarin therapy in the control group. In the PREVAIL trial, 407 subjects were randomized in a 2:1 fashion to either the WATCHMAN device or control, which consisted of either initiation or continuation of warfarin therapy with a target international normalized ratio (INR) of 2.0 to 3.0. Subjects had nonvalvular AF and required treatment for prevention of thromboembolism, based on a $CHADS_2$ score of 2 or higher (or ≥1 with other indications for warfarin therapy based on American College of Cardiology/American Heart Association/European Society of Cardiology guidelines), and were eligible for warfarin therapy. In the WATCHMAN group, warfarin and low-dose aspirin were continued until 45 days post-procedure; if a follow-up echocardiogram at 45 days showed occlusion of the LAA, warfarin therapy could be discontinued. Subjects who discontinued warfarin were treated with aspirin and clopidogrel for six months post-device implantation, and with 325 mg aspirin indefinitely after that. Three non-inferiority primary efficacy end points were specified: (1) occurrence of ischemic or hemorrhagic stroke, cardiovascular or unexplained death, and systemic embolism (18-month rates); (2) occurrence of late ischemic stroke and systemic embolization (beyond seven days post-randomization, 18-month rates); and (3) occurrence of all-cause death, ischemic stroke, systemic embolism, or device- or procedure-related events requiring open cardiac surgery or major endovascular intervention (e.g., pseudoaneurysm repair, arteriovenous fistula repair, or other major endovascular repair) occurring within seven days of the procedure or by hospital discharge, whichever was later. The 18-month event rates were determined using Bayesian statistical methods to integrate data from the PROTECT-AF study. The first primary end point, the 18-month modeled RR between the device and control groups was 1.07 (95% CrI, 0.57 to 1.89). Because the upper bound of the 95% CrI was above the preset non-inferiority margin of 1.75, the non-inferiority criteria were not met. For the second primary end point of late ischemic stroke and systemic embolization, the 18-month RR between the device and control groups was 1.6 (95% CrI, 0.5 to 4.2), with an upper bound of the 95% CrI above the preset non-inferiority margin of 2.0. The rate difference between the device and control groups was 0.005 (95% CrI, -0.019 to 0.027). The upper bound of the 95% CrI was lower than the non-inferiority margin of 0.0275, so the non-inferiority criterion was met for the rate difference. For the third primary end point, major safety issues, the non-inferiority criterion was met.

Reddy et al (2012) reported Longer-term follow-up from the PROTECT AF. At a mean follow-up of 2.3 years, the results were similar to the initial report. The relative risk for the composite primary outcome in the WATCHMAN group, compared with the warfarin group, was 0.71, and this met non-inferiority criteria with a confidence of greater than 99%. Complications were more common in the WATCHMAN group, with an estimated rate of 5.6% per year, compared with 3.6% per year in the warfarin group.

Holmes et al (2009) conducted a randomized, unblinded trial that evaluated the non-inferiority of an LAA closure device, compared with warfarin, for stroke prevention in AF. The single RCT published is the PROTECT-AF study, the trial randomized 707 patients from 59 centers in the U.S. and Europe to the WATCHMAN device or warfarin treatment in a 2:1 ratio. Mean follow-up was 18±10 months. The primary efficacy outcome was a composite end point of stroke (ischemic or hemorrhagic), cardiovascular or unexplained death, or systemic embolism. There was also a primary safety outcome, which was a composite end point of excessive bleeding (intracranial or gastrointestinal bleeding) and procedure-related complications (pericardial effusion, device embolization, procedure-related stroke). The primary efficacy outcome occurred at a rate of 3.0 per 100 patient years in the LAA closure group, compared with 4.9 per 100 patient years in the warfarin group (rate ratio (RR), 0.62; 95% credible interval (CrI), 0.35 to 1.25). Based on these outcomes, the probability of noninferiority was greater than 99.9%. For the individual components of the primary outcome, cardiovascular/ unexplained death and hemorrhagic stroke were higher in the warfarin group. In contrast, ischemic stroke was higher in the LAA closure group at 2.2 per 100 patient years, compared with 1.6 per 100 patient years in the warfarin group (RR=1.34; 95% Crl, 0.60 to 4.29). The primary safety outcome occurred more commonly in the LAA closure group, at a rate of 7.4 per 100 patient years, compared with 4.4 per 100 patient years in the warfarin group (RR=1.69; 95% CrI, 1.01 to 3.19). The higher adverse event rates for the LAA closure group were primarily the result of early adverse events associated with placement of the device. The most frequent type of complication related to LAA closure device placement was pericardial effusion requiring intervention, which occurred in 4.8% of patients (22/463).

Amplatzer Amulet Occluder

Lakkireddy et al (2021) conducted a randomized control trial was conducted to evaluate the safety and effectiveness of the dual-seal mechanism of the Amulet LAA Occluder compared to the Watchman device (Amplatzer Left Atrial Appendage Occluder IDE Trial). Patients with nonvalvular atrial fibrillations at increased risk of stroke were randomly assigned (1:1) to undergo percutaneous implantation of a LAA occlude (Amulet or Watchman device). The primary endpoints included safety, effectiveness, and the rate of LAA occlusion at 45 days. Prespecified secondary endpoints included a composite of all strokes, systemic embolism, or cardiovascular/unexplained death at 18 months, major bleeding at 18 months and superiority test of the three primary end points. A total of 1878 patients were enrolled; the Amulet occlude was noninferior to the Watchman device for primary safety end point 14.5% versus 14.7%. Procedure-related complications were higher for the Amulet Occluder 4.5% versus 2.5%, largely related to more frequent pericardial effusion and device embolization. The Amulet Occluder was noninferior to the Watchman device for the primary effectiveness end point 2.8% versus 2.8%, and the composite of stroke, systemic embolism, or cardiovascular/unexplained death 5.6% versus 7.7%. The rate of major bleeding was similar between groups 11.6% versus 12.3%. LAA occlusion was higher for the Amulet Occluder than for the Watchman device 98.9% versus 96.8%. The Amulet was noninferior for safety and effectiveness of stroke prevention for nonvalvular atrial fibrillation compared with the Watchman device and superior for LAA occlusion. Procedure related complications were higher with the Amulet Occluder and decreased with operator experience.

Whitlock et al (2021) reported the results of the Left Atrial Appendage Occlusion Study (LAAOS) III that randomized 4,811 individuals with preexisting AF to LAA occlusion, or no occlusion scheduled to undergo cardiac surgery. Following post-randomization exclusions prior to surgery, 2,379 individuals were included in the occlusion group and 2,411 were included in the no occlusion group. The treating surgeon selected occlusion method. Among those with data regarding the occlusion method, 15% underwent LAA occlusion with an epicardial closure device (e.g., AtriClip). The primary outcome was the incidence of ischemic stroke or systemic arterial embolism. At a mean 3.8 years follow-up, occlusion was associated with a significant reduction in risk of the primary outcome when compared with no occlusion, without an increased risk of post-procedural bleeding or mortality. Occlusion appeared to result in greater risk reduction among those using either oral anticoagulation DOAC or vitamin K antagonist therapy at baseline than in those not on anticoagulant therapy. Anticoagulant use was 83% in the occlusion group and 81% in the no occlusion group at the time of hospital discharge, and the majority of study participants in both groups continued to use anticoagulants at 1- (80% and 79%), 2- (77% and 78%), and 3-year follow-up (75% and 78%). In conclusion among the individuals with AF who had cardiac surgery completed, most continued antithrombotic therapy. The risk of ischemic stroke or systemic embolism was lower with concomitant LAAO performed during cardiac surgery than without it.

Nietlispach et al (2013) reported a 10-year single center study on the experience with Amplatzer devices for LAA occlusion. The study included 152 patients from a single institution in Europe. Short-term complications occurred in 9.8% (15/152) of patients. Longer-term adverse outcomes occurred in 7% of patients, including two strokes, one peripheral embolization, and four episodes of major bleeding. Device embolization occurred in 4.6% (7/152) of patients. Other, smaller series of patients treated with the Amplatzer device include a series from several European studies and one from China with small sample sizes. All of these series reported high procedural success, but also reported various complications such as vascular complications, air embolism, esophageal injury, cardiac tamponade, and device embolization.

Wiebe et al (2013) reported results of a retrospective cohort of 60 patients with NVAF who had a CHA_2DS_2-VASc score of at least 1 and contraindications to warfarin anticoagulation, and who underwent percutaneous LAA closure with the Amplatzer device. Contraindications to warfarin were defined as the contraindications identified on the warfarin product label, a history of severe bleeding while receiving anticoagulant therapy, and a history of bleeding tendencies in the absence of anticoagulation or blood dyscrasia, along with the inability to maintain a stable INR, a known hypersensitivity to warfarin, or a high-risk of falling. Patients received heparin during the closure procedure; they were maintained on clopidogrel for three months post-procedure, and daily aspirin indefinitely. Device implantation was successful in 95% of patients. Over a median follow-up of 1.8 years, no patients experienced a stroke. The rate of major bleeding complications was 1.9% during the year of follow-up.

AtriClip

Wang et al (2024) conducted a prospective study aimed to evaluate the clinical outcomes of thoracoscopic left atrial appendage occlusion (LAAO) using the AtriClip PRO2 device. The study included 144 procedures; 56 standalone and 88 performed alongside other minimally invasive

surgeries, all by a single surgeon. The results showed no mortality or major complications, with a 100% success rate in complete LAA closure and 87% follow-up imaging completion. Patients who underwent standalone procedures and discontinued anticoagulation experienced no thromboembolic events over 180 patient-years of follow-up. The findings support the safety and efficacy of thoracoscopic AtriClip placement, suggesting it as a reliable alternative to percutaneous methods, with future randomized trials recommended for comparative evaluation.

Lariat Device

Bartus et al (2012) conducted the largest case series on the efficacy of the lariat device for LAA closure. This study enrolled 89 patients with AF and either a contraindication to warfarin or previous warfarin failure. A total of 85/89 (96%) had successful left atrial ligation, and 81/89 (91%) had complete closure immediately. There were three access-related complications, two cases of severe pericarditis post-operatively, one late pericardial effusion, and two cases of unexplained sudden death. There were two late strokes, which the authors did not attribute to an embolic source. At one-year follow-up, complete closure was documented by echocardiography in 98% of available patients (n=65). In a smaller, earlier series from the same research group, 13 patients were treated with the Lariat device, 11 of whom were treated as part of percutaneous radiofrequency ablation for AF. One of the 11 procedures was terminated due to unsuccessful placement, and the other 10 procedures were successful, with complete closure verified on echocardiography. There was one procedural complication in which the snare was unable to be removed and needed to be retrieved by thoracoscopy.

PROFESSIONAL GUIDELINE(S)

The American College of Cardiology/American Heart Association (ACC/AHA) 2023 Guideline for the Diagnosis and Management of Atrial Fibrillation (Joglar, et al., 2023) lists the following recommendations:

Concomitant Surgical LAA Exclusion/Excision in Individuals with AF:

- 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 anticoagulation, is indicated to reduce the risk of stroke and systemic embolism. (Class of Recommendations (COR):1; Level of Evidence (LOE): A)
- In patients with AF undergoing cardiac surgery and LAA exclusion, a surgical technique resulting in absence of flow across the suture line and a stump of <1 cm as determined by intraoperative transesophageal echocardiography should be used. (COR:1; LOE: 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. (COR:2b; LOE: A)

Percutaneous Approaches to Occlude the LAA:

- In patients with AF, a moderate to high risk of stroke (CHA_2DS_2 score ≥2), and a contraindication to long-term oral anticoagulation due to a nonreversible cause, percutaneous LAAO (pLAAO) is reasonable. (COR:2a; LOE: B-NR)
- In patients with AF and a moderate to high risk of stroke and a high risk of major bleeding on oral anticoagulation, pLAAO may be a reasonable alternative to oral anticoagulation based on patient preference, with careful consideration of procedural risk and with the understanding that the evidence for oral anticoagulation is more extensive. (COR:2b; LOE: B-R)

In 2021, the National Institute on Health and Care Excellence (NICE) recommended consideration of LAA occlusion if anticoagulation is contraindicated or not tolerated.

The updated 2016 European Society of Cardiology (ESC) Guidelines, developed in collaboration with the European Association for Cardio-Thoracic Surgery, EACTS, recommend consideration of percutaneous LAAC for patients at high stroke risk with contraindications to long-term oral anticoagulation.

REGULATORY STATUS

The United States Food and Drug Administration (FDA) regulates LAAO devices as medical devices. All LAAO devices including related components require FDA approval before marketing and use in the United States to ensure they are safe and effective for human use. Refer to the FDA Medical Device website. Available from: https://www.fda.gov/medical-devices [accessed 2025 Aug 27]

The FDA lists the most serious type of medical device recalls as well as early alert communications about corrective actions being taken by companies that the FDA believes are likely to be the most serious type of recalls on our website by the date that the FDA posts the information on our website. Available from: Medical Device Recalls | FDA [accessed 2025 Aug 27]

Percutaneous devices that are currently approved by the FDA include:

- Watchman device LAA closure device, (Watchman and Watchman FLX) (Boston Scientific Corporation, Marlborough, MA), received FDA approval in March 2015.
- The WATCHMAN FLX device received FDA approval in July 2020
- The Amplatzer Amulet LAA occlude (Abbott, Minneapolis, MN), received FDA approval in August 2021.

The Amplatzer cardiac plug (St. Jude Medical, Minneapolis, MN), is FDA-approved for closure of atrial septal defects but has not received FDA approval for LAA closure.

CODE(S)

- Codes may not be covered under all circumstances.
- Code list may not be all inclusive (AMA and CMS code updates may occur more frequently than policy updates).
- (E/I) =Experimental/Investigational
- (NMN)=Not medically necessary/appropriate

CPT Codes

Code	Description
33267 (E/I)	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 methods (e.g., excision, isolation via stapling, oversewing, ligation, plication, clip) (List separately in addition to code for primary procedure)
33269 (E/I)	Exclusion of left atrial appendage, thoracoscopic, any method (e.g., excision, isolation via stapling, oversewing, ligation, plication, clip)
33340	Percutaneous transcatheter closure of the left atrial appendage with endocardial implant, including fluoroscopy, transseptal puncture, catheter placement(s), left atrial angiography, left atrial appendage angiography, when performed, and radiological supervision and interpretation

HCPCS Codes

Code	Description
Not Applicable	

ICD10 Codes

Code	Description
I48.0-I48.21	Atrial fibrillation (code range)
I48.91	Unspecified atrial fibrillation

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SEARCH TERMS

Not Applicable

CENTERS FOR MEDICARE AND MEDICAID SERVICES (CMS)

Percutaneous Left Atrial Appendage Closure (LAAC) (NCD 20.34) [accessed 2025 Aug 27]

PRODUCT DISCLAIMER

- Services are contract dependent; if a product does not cover a service, medical policy criteria do not apply.
- If a commercial product (including an Essential Plan or Child Health Plus product) covers a specific service, medical policy criteria apply to the benefit.
- If a Medicaid product covers a specific service, and there are no New York State Medicaid guidelines (eMedNY) criteria, medical policy criteria apply to the benefit.
- If a Medicare product (including Medicare HMO-Dual Special Needs Program (DSNP) product) covers a specific service, and there is no national or local Medicare coverage decision for the service, medical policy criteria apply to the benefit.
- If a Medicare HMO-Dual Special Needs Program (DSNP) product DOES NOT cover a specific service, please refer to the Medicaid Product coverage line.

POLICY HISTORY/REVISION

Committee Approval Dates

08/20/15, 10/20/16, 11/16/17, 11/15/18, 11/21/19, 11/19/20, 11/18/21, 07/21/22, 09/21/23, 09/19/24, 09/18/25

Date	Summary of Changes
09/18/25	• Annual review; policy intent unchanged.
01/01/25	• Summary of changes tracking implemented.
08/20/15	• Original effective date