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MEDICAL POLICY – 2.02.519

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

BCBSA Ref. Policy:	2.02.26	
Effective Date:	**Feb. 5, 2027***	RELATED MEDICAL POLICIES:
Last Revised:	Oct. 13, 2026	None
Replaces:	N/A	
*View the current policy here.		

Select a hyperlink below to be directed to that section.

POLICY CRITERIA | DOCUMENTATION REQUIREMENTS | CODING
RELATED INFORMATION | EVIDENCE REVIEW | REFERENCES | HISTORY

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Introduction

The heart is divided into two upper and two lower chambers. Atrial fibrillation, also called a-fib, occurs when the heart's upper chambers beat irregularly—and often rapidly. Because blood isn't pumped out the way that 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. Blood thinners are the usual method of preventing blood clots in people with a-fib. If taking a blood thinner poses too much risk or a person can't tolerate this medication, placing a device in the heart is a different way of helping to prevent stroke. This device seals off the left atrial appendage. Should a clot develop, the device blocks it from entering the bloodstream. This policy describes when a left atrial appendage closure device is considered medically necessary.

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	Medical Necessity
Percutaneous left atrial appendage closure device • **Amplatzer Amulet** • **Watchman)**	**Percutaneous endovascular closure (occlusion) of the left atrial appendage (pLAAC/LAAO) using a device that has received US Food and Drug Administration (FDA) Premarket Approval (PMA) is considered medically necessary when ALL of the following criteria are met (See Related Information):** • The individual has non-valvular atrial fibrillation • Has an elevated annual risk of stroke based on a CHA_2DS_2-VASc score greater than or equal to in males or greater than or equal to 3 in females (See **Related Information**) • Is a candidate for long-term anticoagulation therapy based upon their estimated risk of stroke and other systemic thromboembolic events (See **Related Information**) • Has a contraindication to long term oral anticoagulation (OAC) due to a nonreversible cause • Has a high risk of major bleeding on long-term OAC with HAS-BLED score greater than or equal to 3, indicating an elevated risk of bleeding while on anticoagulation (See **Related Information**) **The use of a device with FDA approval for percutaneous left atrial appendage closure (e.g., the Watchman or Amplatzer Amulet) for stroke prevention in individuals who do not meet the above criteria is considered investigational.**

Device	Investigational
Other percutaneous left atrial appendage closure devices	**The use of any other percutaneous left atrial appendage closure devices, including but not limited to the Lariat and Amplatzer Cardiac Plug devices is considered investigational.**

Documentation Requirements
The individual's medical records submitted for review for all conditions should document that medical necessity criteria are met. The record should include ALL of the following:

Documentation Requirements
• Name of the Food and Drug Administration (FDA) device to be used • Diagnosis of non-valvular atrial fibrillation with CHA_2DS_2-VASc score greater than or equal to 2 in males or greater than or equal to 3 in females, supporting the indication for long-term anticoagulation therapy • Documentation of a contraindication to long-term oral anticoagulation (OAC) due to a nonreversible cause • High risk of major bleeding on long-term OAC with HAS-BLED score greater than or equal to 3

Coding

Code	Description
CPT	
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

Note: CPT codes, descriptions and materials are copyrighted by the American Medical Association (AMA). HCPCS codes, descriptions and materials are copyrighted by Centers for Medicare Services (CMS).

Related Information

In individuals with atrial fibrillation, the balance of risk of stroke and systemic thromboembolism and risk of sustained use of anticoagulation must be assessed on an individual basis in order to determine the potential benefits associated with using an endovascular closure (occlusion) of the left atrial appendage {LAAC/LAAO) device that has received US Food and Drug Administration (FDA) Premarket Approval (PMA) for stroke prevention. There is overlap between several of the risk factors for stroke and bleeding while on anticoagulation therapy.

Risk of Stroke

The 2018 American College of Chest Physicians guidelines (updated from 2012) recommend that CHA_2DS_2VASc be used to estimate the annual risk of thromboembolic event (primarily ischemic

stroke) in non-anticoagulated individuals with non-valvular atrial fibrillation (AF). Guidelines recommend against giving antithrombotic therapy to individuals initially identified as having a low stroke risk. (See **Table 1**).

Table 1: $CHADS_2$ and CHA_2DS_2-VASc Scores to Predict Ischemic Stroke Risk in Individuals with Atrial Fibrillation

Letter	Clinical Characteristic	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	2 (CHA2DS2-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)[1,] and January et al (2014)[2]

Table 2: CHA2DS2-VASc Scores and Annual Stroke Risk Estimates in Individuals with Atrial Fibrillation*

CHA2DS2-VASc Score	Annual Stroke Risk (CHA2DS2-VASc)[a]	Annual Stroke Risk (CHADS2)[b]
0	0%	1.9%
1	1.35%c	2.8%
2	2.2%	4.0%

CHA2DS2-VASc Score	Annual Stroke Risk (CHA2DS2-VASc)[a]	Annual Stroke Risk (CHADS2)[b]
3	3.2%	5.9%
4	4.0%	8.5%
5	6.7%	12.5%
6	9.8%	18.2%
7	9.6%	—
8	6.7%	—
9	15.2%	—

* Adapted from Stroke Manual. CHA2DS2-VASc score.[3]

a CHA2DS2-VASc annual stroke risk estimates adapted from Eckman et al (2011).[4]

b CHADS2 annual stroke risk estimates from Gage et al (2001).[5]

Note: according to some reports, the annual stroke risk at a CHA2DS2-VASc score of 1 may be lower (0.2%-0.7%).[6T]

Risk of Bleeding

Bleeding is the primary risk associated with systemic anticoagulation. The HAS-BLED score has been validated to assess the annual risk of significant bleeding in individuals with atrial fibrillation treated with warfarin. Scores range from 0 to 9, based on a number of clinical characteristics (see **Table 3**).

Table 3: Clinical Components of the HAS-BLED Bleeding Risk Score

Letter	Clinical Characteristic	Points Awarded
H	Hypertension	1
A	Abnormal renal and liver function (1 point each)	1 or 2
S	Stroke	1
B	Bleeding	1
L	Labile international normalized ratios	1
E	Elderly (>65 y)	1
D	Drugs or alcohol (1 point each)	1 or 2

Adapted from Lip et al. (2010)[7], Pisters et al (2010)[8],

HAS-BLED: Hypertension, Abnormal renal/liver function, Stroke, Bleeding history or predisposition, Labile INR (international normalized ratio), Elderly, Drugs/alcohol concomitantly.

The risk of major bleeding in individuals with scores of 3, 4, and 5 has been reported at 3.74 per 100 individual-years, 8.70 per 100 individual-years, and 12.5 per 100 individual-years, respectively. Scores of 3 or greater are considered to be associated with a high risk of bleeding, potentially signaling the need for closer monitoring of individuals for adverse events, closer monitoring of international normalized ratio with warfarin use, or differential dose selections of oral anticoagulants or aspirin.

Beyond risk of stroke and systemic embolism (CHA2DS2-VASc score) and bleeding risk (HAS-BLED score), additional individual-specific factors may inform the individual assessment of candidacy for LAAC.

A 2026 American College of Cardiology (ACC) Scientific Statement on Direct Oral Anticoagulants in Primary and Secondary Prevention of Thrombotic Events lists several clinically relevant circumstances in which direct oral anticoagulants (DOAC) use may be limited or contraindicated. These include individuals with chronic kidney disease stage 4 or 5 or those on dialysis, and hepatic dysfunction graded using Child-Pugh classification. Advanced age and frailty with attendant risk for falls, excessive body weight (body mass index ≥ 40 kg/m^2), and history of prior major bleeding events are also relevant considerations. Polypharmacy and DOAC drug–drug interactions are factors that may affect both the tolerability of long-term anticoagulation and the relative benefit of LAAC as an alternative.

Evidence Review

Description

Stroke prevention in individuals 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), also referred to as left atrial appendage occlusion (LAAO). Two types of left atrial appendage devices (the Watchman and Amplatzer Amulet devices) have approval from the US Food and Drug Administration (FDA) for stroke prevention in individuals with atrial fibrillation (AF).

Background

Atrial Fibrillation and Stroke

Atrial Fibrillation (AF) is the most common type of irregular heartbeat, affecting at least 2.7 million people in the US Risk of AF has been found to be lower in Black, Hispanic and Asian individuals relative to White individuals, including following adjustment for demographic and AF risk factors.[9,10] Stroke is the most serious complication of AF. The estimated incidence of stroke in nontreated 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.[11,12] 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 individuals with AF is evaluated using several factors. Warfarin or newer anticoagulant medications, including dabigatran, rivaroxaban, apixaban, and edoxaban are options for stroke prevention. In nonvalvular AF (NVAF), 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. Bleeding is the primary risk associated with systemic anticoagulation. Risk scores have been developed to estimate the risk of significant bleeding in individuals treated with systemic anticoagulation, such as the HAS-BLED score (see **Table 3**), which has been validated to assess the annual risk of significant bleeding in individuals with AF treated with warfarin.[7] 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 individuals for adverse risks, closer monitoring of international normalized ratios, or differential dose selections of oral anticoagulants or aspirin.[2]

Surgery

Surgical removal, or exclusion, of the LAA is often performed in individuals with AF who are undergoing open heart surgery for other reasons. Percutaneous left atrial appendage closure (LAAC) closure 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, individuals receive anticoagulation with warfarin or alternative agents for approximately one to two months. After this period, individuals 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.[13]

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.[14] 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.

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.[15] This was based on an analysis of registry data from 49,357 individuals who underwent LAA closure with the Watchman device.[16] 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 individuals 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 individuals 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. Most studies evaluating percutaneous LAAC devices have included individuals who are eligible for anticoagulation.

Summary of Evidence

For individuals who have atrial fibrillation (AF) who are at increased risk for embolic stroke who receive a US Food and Drug Administration (FDA)-approved percutaneous left atrial appendage closure (LAAC) device (e.g., the Watchman or Amulet device), the evidence includes systematic reviews, randomized controlled trials (RCTs) and observational studies. Relevant outcomes are overall survival, morbid events, and treatment-related morbidity. The most relevant evidence for the Watchman device comes from three industry-sponsored RCTs (PROTECT AF and PREVAIL, and CHAMPION-AF) comparing the Watchman device with anticoagulation. One trial (PROTECT AF) reported noninferiority on a composite outcome of stroke, cardiovascular/unexplained

death, or systemic embolism after two years of follow-up, with continued benefits with the Watchman device after four years of follow-up. The second trial (PREVAIL) 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. Individual-level meta-analyses at five-year follow-up for the two warfarin-era 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 also associated with lower rates of major bleeding, particularly hemorrhagic stroke, and mortality over the long term. Among individuals with AF who are candidates for anticoagulation, an RCT (CHAMPION-AF) showed that the use of the Watchman FLX device was noninferior to anticoagulation with direct oral anticoagulants (DOACs) with respect to a composite of death from cardiovascular causes, stroke, or systemic embolism, and was superior to anticoagulants for non-procedure-related bleeding at three years. Evidence for the Amplatzer Amulet device comes from a systematic review and two RCTs (SWISS-APERO and Amulet IDE) comparing the Amulet and Watchman devices, one of which (SWISS-APERO) 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 three and five-year follow-up, clinical outcomes remained similar between individuals in the Amulet group and the Watchman group, with a higher percentage of Amulet users not using oral anticoagulation. A secondary analysis of the Amulet IDE trial reported a five-year major bleeding rate of 18% following LAAC, with the highest annualized risk in the first six months after implantation; major bleeding was strongly associated with stroke, cardiovascular death, and all-cause mortality, reinforcing the importance of individual risk assessment in individual selection. In a systematic review, there was no statistically significant difference between the Amulet and Watchman devices in the primary outcome of ischemic or hemorrhagic stroke, though results numerically favored the Amulet device; however, the Amulet device was associated with a higher risk of pericardial effusion compared with the Watchman device. One additional RCT (PRAGUE-17) evaluated the use of either the Amplatzer Amulet or Watchman device versus anticoagulants; subgroup analyses according to device were not performed. After up to four 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. Another noninferiority RCT (CLOSURE-AF) compared catheter based LAAC using one of several devices (Watchman, Watchman FLX, Amplatzer Amulet or Cardiac Plug, or LAmbre device) with physician directed best medical care, finding that the LAAC group was not noninferior to

physician-directed best medical care with regard to a composite end point of stroke, systemic embolism, major bleeding, or cardiovascular or unexplained death. Subgroup analysis by device type was not performed. Three 2026 meta-analyses incorporating the DOAC-era trials (CHAMPION-AF, CLOSURE-AF, OPTION, and PRAGUE-17) reached broadly consistent conclusions. There were no significant differences between LAAC and OAC in all-cause death, cardiovascular death, hemorrhagic stroke, or systemic embolism. There was a consistently higher point estimate for ischemic stroke risk with LAAC that reached statistical significance in two analyses. Across all three meta-analyses, LAAC significantly reduced nonprocedure-related bleeding. These findings support a shared decision-making approach weighing the bleeding reduction benefit of LAAC against a potentially higher ischemic stroke risk relative to DOAC therapy. The evidence is sufficient to determine that the technology results in an improvement in the net health outcome.

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 (e.g., Lariat or Amplatzer Cardiac Plug), the evidence includes two RCTs 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 individuals undergoing LAAC with the Lariat device with individuals 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.

Ongoing and Unpublished Clinical Trials

Some currently ongoing and unpublished trials that might influence this policy are listed in **Table 4**.

Table 4. Summary of Key Trials

NCT No.	Trial Name	Planned Enrollment	Completion Date
Ongoing			
NCT06686485	cOncomitant Left Atrial APpendage Closure and Pulsed Field AblaTION-Asia	433	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 2031
NCT06521463[a]	WATCHMAN FLX™ Pro Left Atrial Appendage Closure Device With Alternative Post-Implant Monotherapy	1857	Jan 2027
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	Clinical Trial of Atrial Fibrillation Patients Comparing Left Atrial Appendage Occlusion Therapy to Non-vitamin K Antagonist Oral Anticoagulants	2650	Apr 2031
Unpublished			
NCT03276169	Left Atrial Function Changes after Left Atrial Appendage Closure in Patients with Persistent Atrial Fibrillation	105	Nov 2020 (updated Mar 2021)
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 2026)

NCT: national clinical trial

[a] indicates industry-sponsored study

Clinical Input Received 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 one physician specialty society (two responses) and four academic medical centers, one of which provided four responses, for a total of eight responses, while this policy was under review in 2015. Input generally supported the use of a left atrial appendage closure device approved by the US Food and Drug Administration for individuals 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

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 (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 Cardiology

In 2026, the American College of Cardiology (ACC) published a scientific statement on direct oral anticoagulants (DOACs) in the primary and secondary prevention of thrombotic events.[93] With respect to left atrial appendage closure (LAAC), the statement includes the following consensus recommendation: LAAC may be considered to reduce thromboembolic events in people with

prior intracerebral hemorrhage and atrial fibrillation who are considered unsuitable for long-term oral anticoagulation therapy (e.g., people with imaging or pathological evidence of cerebral amyloid angiopathy).

American College of Chest Physicians

In 2018, the American College of Chest Physicians (CHEST) guideline made the following recommendation regarding LAA occlusion and oral anticoagulation (OAC): "In patients with AF at high risk of ischemic stroke who have absolute contraindications for OAC, we suggest using LAA occlusion (Weak recommendation, low-quality evidence)."[1]

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.[94]

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, non-randomized). No other LAA closure devices are mentioned in the guideline. Another guideline update was published in 2023.[95] 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.[96] 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.[97] 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."

In collaboration with the Society for Cardiovascular Angiography & Interventions, the HRS published a clinical practice guideline on transcatheter LAAC in 2025.[98] The following recommendations on non-valvular atrial fibrillation (NVAF) relevant to this policy were made in the guideline:

- "For patients with NVAF and contraindication to OAC, the SCAI/HRS guideline panel suggests LAAO over no therapy (neither OAC nor LAAO) (conditional recommendation, very low certainty evidence)."
- "For patients with NVAF who have decided to pursue stroke prevention treatment, the SCAI/HRS guideline panel suggests OAC or LAAO as treatment options." Additional relevant remarks regarding this recommendation are as follows: "Although most patients are offered stroke prevention with OAC, those with elevated bleeding risk, prior bleeding complications, or strong preferences to avoid long-term anticoagulation would reasonably choose LAAO over OAC. LAAO may be inappropriate for patients with less than 1 year of quality life expectancy."

American College of Cardiology/American Heart Association/American College of Clinical Pharmacy/Heart Rhythm Society

The 2023 American College of Cardiology/American Heart Association/American College of Clinical Pharmacy/Heart Rhythm Society (ACC/AHA/ACCP/HRS) guideline identifies circumstances in which long-term oral anticoagulation (OAC) is contraindicated due to a nonreversible cause. These include one or more of the following:

- Severe bleeding due to a nonreversible cause involving:
  - Gastrointestinal system
  - Pulmonary system
  - Genitourinary system
- Spontaneous intracranial or intraspinal bleeding due to a nonreversible cause

- Serious bleeding related to recurrent falls when the cause of the falls is not considered treatable[95]

The guideline separately recognizes high risk of major bleeding on OAC as a circumstance in which percutaneous left atrial appendage occlusion may be a reasonable alternative to long-term OAC. Bleeding risk scores may help identify factors associated with bleeding but should not be used in isolation to determine eligibility for OAC.[95]

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[99]:

"LAAC devices are covered when the device has received 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 meets 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."

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

Regulatory Status

Watchman Device

In 2002, the PLAATO system (ev3 Endovascular) was the first device to be approved by 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.[17] In 2020, the Watchman FLX device (Boston Scientific) was approved by the FDA based on the single-arm, nonrandomized PINNACLE FLX study.[13]

In September 2023, the Watchman FLX Pro device (Boston Scientific) received FDA approval (PMA Supplement P130013/S057) as a next-generation device built upon the Watchman FLX platform, featuring a thromboresistant polymer coating intended to reduce device-related thrombus, visualization markers, and an expanded 40mm size option. The initial indication was the same as the Watchman FLX — reducing thromboembolism risk from the LAA in NVAF individuals who require an alternative to oral anticoagulation. In July 2025, the FDA approved a label expansion for both the Watchman FLX and Watchman FLX Pro (PMA Supplement P130013/S074) to include individuals who have undergone catheter ablation for NVAF (concomitantly or sequentially with device implantation), based on results from the OPTION trial. This supplement also updated the post-implant drug regimen to allow NOAC monotherapy as a labeled option.

Regulatory details are summarized in **Table 5**.

Table 5. Watchman Device Cleared by the US Food and Drug Administration

Application	Manufacturer	FDA Cleared Indication	Description	FDA Product Code	Clearance	Date
Watchman LAA Closure Technology	Boston Scientific	Reduce the risk of thromboembolism from the LAA in individuals with NVAF who: are at increased risk for stroke and systemic embolism based on CHADS2 or CHA2DS2-VASc scores and are recommended for anticoagulation therapy; are deemed by their physicians to be suitable for warfarin; and have an appropriate rationale to seek a non-pharmacologic alternative to warfarin, taking into account the safety and effectiveness of the device compared to warfarin.	First-generation Watchman device; approved via PROTECT AF RCT	NGV	PMA (P130013)	March 13, 2015
Watchman FLX LAA Closure Device	Boston Scientific	Reduce the risk of thromboembolism from the LAA in individuals with NVAF who:1) Are at increased risk	Next-generation device; approved via single-arm PINNACLE FLX	NGV	PMA Supplement (P130013/S035)	July 21, 2020

		for stroke and systemic embolism based on CHADS2 or CHA2DS2-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 non-pharmacologic alternative to anticoagulation therapy, taking into account the safety and effectiveness of the device compared to anticoagulation therapy.	study; expanded indication to include non-warfarin OAC			
Watchman FLX Pro LAA Closure Device	Boston Scientific	Reduce the risk of thromboembolism from the LAA in individuals with NVAF who require an alternative to oral anticoagulation therapy; and (per July 2025 label expansion) in individuals following catheter ablation for NVAF (concomitantly or sequentially with	Third-generation device; features thromboresistant polymer coating, visualization markers, and 40mm size option; approved without new RCT (built on Watchman FLX platform); label expanded in 2025 to include	NGV	PMA Supplement (P130013/S057); label expansion PMA Supplement (P130013/S074)	September 6, 2023; label expansion July 18, 2025

		device implantation).	post-ablation individuals per OPTION trial			

IDE: Investigational Device Exemption; LAA: left atrial appendage; NVAF: nonvalvular atrial fibrillation; OAC: oral anticoagulant; PMA: Premarket Approval; RCT: randomized controlled trial.

Amplatzer Amulet Device

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).[14]
Regulatory details are summarized in **Table 6**.

Table 6. Amplatzer Amulet Device Cleared by the US Food and Drug Administration

Application	Manufacturer	FDA Cleared Indication	Description	FDA Product Code	Clearance	Date
Amplatzer Amulet LAA Occluder	Abbott	The device is a percutaneous transcatheter device intended to reduce the risk of thrombus embolization from the LAA in individuals who have NVAF and who are at increased risk for stroke and systemic embolism based on CHADS2 or CHA2DS2-VASc scores, are	Approved via Amulet IDE RCT	NGV	PMA (P200049)	August 14, 2021

		suitable for short term anticoagulation therapy, and have appropriate rationale to seek a non-pharmacologic alternative to oral anticoagulation, taking into consideration the safety and effectiveness of the device.				

IDE: Investigational Device Exemption; LAA: left atrial appendage; NVAF: nonvalvular atrial fibrillation; PMA: Premarket Approval.

FDA product code: NGV.

Several other devices are being evaluated for LAA occlusion but are not approved in the US for percutaneous LAAC. In 2006, the Lariat Loop Applicator device (SentreHEART), 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) and WaveCrest (Johnson & Johnson Biosense Webster) have CE approval in Europe for LAAC but are not currently approved in the US for this indication.

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History

Date	Comments
06/13/11	Add to Cardiology Section - New medical policy created with literature search; procedure considered investigational.
12/29/11	Code 0281T added.
05/22/12	Replace policy. Policy updated with literature review, references 2-4, 6-9, 11, 12 added. Policy title and policy statements revised to include percutaneous – no other change to policy statement.
09/17/12	Update Coding Section – ICD-10 codes are now effective 10/01/2014.
05/28/13	Replace policy. Policy updated with literature review through January 2013, references 2, 12-20 added. Policy statement unchanged.
09/23/14	Annual Review. Policy updated with literature review through June 5, 2014. References 1-3, 12-14, 17, 25-29, 31-32, and 34 added. Policy statement unchanged.
12/08/15	Annual Review. Policy updated with literature review through May 29, 2015; references 2-3, 6, 9, 9, 12, 21, 33, and 43 added; clinical input reviewed. An FDA-approved left atrial appendage closure device is considered medically necessary with conditions.
08/01/16	Annual Review, approved July 12, 2016. Policy updated with literature review through April 30, 2016; references 6-7, 9-11, and 25-27 added. Policy statements unchanged.
01/01/17	Coding update, added new code 33340 effective 1/1/17.
07/01/17	Annual Review, approved June 22, 2017. Policy moved into new format. Policy updated with literature review through March 23, 2017; references 13-18 and 55-56 added. Policy statements unchanged.

Date	Comments
01/01/18	Removed code CPT code 0281T as it was terminated 1/1/17 and replaced with 33340.
08/01/18	Annual Review, approved July 13, 2018. Policy updated with literature review through March 2018; references 16 and 53 added. PLAATO device removed from the policy statement; statements otherwise unchanged. Removed CPT codes 33999 and 93799.
08/01/19	Annual Review, approved July 25, 2019. Policy updated with literature review through March 2019; several references added. Policy statements unchanged.
04/01/20	Delete policy, approved March 10, 2020. This policy will be deleted effective July 2, 2020, and replaced with InterQual criteria for dates of service on or after July 2, 2020.
07/02/20	Delete policy.
11/01/20	Policy reinstated effective February 5, 2021, approved October 13, 2020. Policy updated with literature review through March, 2020; references added. Policy statements unchanged.
08/01/21	Annual Review, approved July 9, 2021. Policy updated with literature review through March 18, 2021; references added. Policy statements unchanged.
08/01/22	Annual Review, approved July 12, 2022. Policy updated with literature review through March 12, 2022; references added. Policy statements updated to include the FDA-approved Amplatzer Amulet device.
08/01/23	Annual Review, approved July 10, 2023. Policy updated with literature review through March 23, 2023; references added. Minor editorial refinements to policy statements; intent unchanged. Changed the wording from "patient" to "individual" throughout the policy for standardization.
08/01/24	Annual Review, approved July 8, 2024. Policy updated with literature review through March 26, 2024; references added. Policy statements unchanged.
08/01/25	Annual Review, approved July 7, 2025. Policy updated with literature review through March 21, 2025; references added. Policy statements unchanged.
11/01/26	Policy 2.02.519 Percutaneous Left Atrial Appendage Closure Devices for Stroke Prevention in Atrial Fibrillation replaced 2.02.26 Percutaneous Left Atrial Appendage Closure Devices for Stroke Prevention in Atrial Fibrillation, approved October 13, 2026; effective for dates of service on or after February 5, 2027, following 90-day provider notification. Policy updated with literature review through July 24, 2026; references added. Policy statements revised for clarity; added specific criteria to the medically necessary statement including: the individual has non-valvular atrial fibrillation, the individual has an elevated annual risk of stroke based on a CHA_2DS_2-VASc score ≥2 in males or ≥3 in females, the individual is a candidate for long-term anticoagulation therapy based upon their estimated risk of stroke and other systemic thromboembolic events, the individual has a contraindication to long term oral anticoagulation (OAC) due to a nonreversible cause, the individual has a high risk of major bleeding on long-term OAC with HAS-BLED score ≥3, indicating an elevated risk of bleeding while on anticoagulation. Table updates: Table 1 CHADS2 and CHA2DS2-VASc Scores to Predict Ischemic Stroke Risk in Individuals with Atrial Fibrillation, Table 3 Clinical Components

Date	Comments
	of the HAS-BLED Bleeding Risk Score. Added Table 2 CHA2DS2-VASc Scores and Annual Stroke Risk Estimates in Individuals with Atrial Fibrillation, Table 5 Watchman Device Cleared by the FDA, Table 6 Amplatzer Amulet Device Cleared by the FDA.

Disclaimer: This medical policy is a guide in evaluating the medical necessity of a particular service or treatment. The Company adopts policies after careful review of published peer-reviewed scientific literature, national guidelines and local standards of practice. Since medical technology is constantly changing, the Company reserves the right to review and update policies as appropriate. Member contracts differ in their benefits. Always consult the member benefit booklet or contact a member service representative to determine coverage for a specific medical service or supply. CPT codes, descriptions and materials are copyrighted by the American Medical Association (AMA). ©2026 Premera All Rights Reserved.

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