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# MEDICAL POLICY – 2.02.26

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

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|---|---|---|
| BCBSA Ref. Policy: | 2.02.26 | |
| Effective Date: | August 1, 2024 | RELATED MEDICAL POLICIES: |
| Last Revised: | July 8, 2024 | None |
| Replaces: | N/A | |

**Select a hyperlink below to be directed to that section.**

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

Clicking this icon returns you to the hyperlinks menu above.

## 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 (e.g., the Watchman)** | **The use of a device with US Food and Drug Administration (FDA) approval for percutaneous left atrial appendage closure (e.g., the Watchman or Amplatzer Amulet) may be considered medically necessary for the prevention of stroke in individuals with atrial fibrillation when the following criteria are met:**<br>• There is an increased risk of stroke and systemic embolism based on $CHADS_2$ or $CHA_2DS_2$-VASc score (see **Table 2**) and systemic anticoagulation therapy is recommended<br>**AND**<br>• The long-term risks of systemic anticoagulation outweigh the risks of the device implantation (see **Related Information**)<br><br>**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 other percutaneous left atrial appendage closure devices, including but not limited to the Lariat and Amplatzer Cardiac Plug devices, for stroke prevention in individuals with atrial fibrillation 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:**<br>• Name of the Food and Drug Administration (FDA) device to be used<br>• $CHADS_2$ or $CHA_2DS_2$-VASc score documenting individual's increased risk of stroke and systemic embolism<br>• Documentation that systemic anticoagulation therapy is recommended AND the long-term risks of systemic anticoagulation outweigh the risks of the device implantation |

## 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

The balance of risks and benefits associated with percutaneous implantation of the Watchman or Amplatzer Amulet device for stroke prevention, as an alternative to systemic anticoagulation, must be made on an individual basis.

Bleeding is the primary risk associated with systemic anticoagulation. A number of risk scores have been developed to estimate the risk of significant bleeding in individuals treated with systemic anticoagulation. An example is the HAS-BLED score, which 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 1**).

### Table 1: 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 Pisters et al (2010) 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 patient-years, 8.70 per 100 patient-years, and 12.5 per 100 patient-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 risks, closer monitoring of international normalized ratio, or differential dose selections of oral anticoagulants or aspirin.

# 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). Two types of left atrial appendage device (the Watchman and Amplatzer Amulet devices) have approval from the US Food and Drug Administration (FDA)for stroke prevention in individuals with 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.[1,2] 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.[3,4] 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. Two commonly used scores, the $CHADS_2$ and the $CHA_2DS_2$-VASc score, are described below in **Table 2**. Warfarin is the predominant agent in clinical use. A number of newer anticoagulant medications, including dabigatran, rivaroxaban, apixaban, and edoxaban have received US Food and Drug Administration (FDA) approval for stroke prevention in nonvalvular AF and 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; however specific reversal agents do not exist for all of these agents. The 2018 American College of Chest Physicians guidelines (updated from 2012) recommend that $CHA_2DS_2$VASc be used to evaluate stroke risk, and individuals 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 individual at every individual contact and that "potentially modifiable bleeding risk factors" should be the initial focus.

## Table 2. $CHADS_2$ 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 |

| Letter | Clinical Characteristics | Points Awarded |
|---|---|---|
| H | Hypertension (resting blood pressure >140/90 mmHg on at least 2 occasions or current antihypertensive pharmacologic treatment) | 1 |
| A | Age ≥75 y | 1 ($CHADS_2$)<br>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)[5] and January et al (2014).[6]

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, 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.[6]

### *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 1 to 2 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.[8] 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.[9] 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 Occlutech (Occlutech) Left Atrial Appendage Occluder has received a CE mark for coverage in Europe. The Cardioblate closure device (Medtronic) is currently being tested in clinical studies.

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.

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.[10] This was based on an analysis of registry data from 49,357 individuals who underwent LAA closure with the Watchman device.[11] 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 postimplantation 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 an 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. The most relevant evidence for the Watchman device comes from two industry-sponsored RCTs comparing the Watchman device with anticoagulation alone. One trial 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 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. Patient-level meta-analyses at five-year follow-up for the two Watchman trials reported that the Watchman device is noninferior to warfarin on the composite outcome of stroke, systemic embolism, and cardiovascular death. Also, the Watchman was associated with lower rates in 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 short-term trial that assessed periprocedural outcomes at 45 days. 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 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. One additional 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 four years of follow-up, the study found LAAC closure 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. Among individuals in which the long-term risk of systemic anticoagulation exceeds the procedural risk of device implantation, the net health outcome will be improved. 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 several nonrandomized comparator studies and uncontrolled observational studies. Relevant outcomes are overall survival, morbid events, and treatment-related morbidity. 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 US 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 3**.

## Table 3. Summary of Key Trials

| NCT No. | Trial Name | Planned Enrollment | Completion Date |
|---|---|---|---|
| **Ongoing** | | | |

| NCT No. | Trial Name | Planned Enrollment | Completion Date |
|---|---|---|---|
| NCT02513797[a] | Left Atrial Appendage Ligation With the LARIAT Suture Delivery System as Adjunctive Therapy to Pulmonary Vein Isolation for Persistent or Longstanding Persistent Atrial Fibrillation | 600 | Mar 2022 (unknown status) |
| 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 | 1512 | Mar 2025 |
| NCT02964208[a] | AMPLATZER LAA Occluder Post Approval Study (PAS) | 1000 | Jun 2023 (active, not recruiting) |
| NCT03309332[a] | OSB Lead-AMPLATZER PFO Occluder New Enrollment PAS | 1214 | Apr 2030 |
| NCT03795298 | Comparison of Anticoagulation with Left Atrial Appendage Closure After AF Ablation (OPTION) | 1600 | Nov 2024 |
| 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 | April 2029 |
| **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 | 3000 | 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

## 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 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)."[5]

## 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.[76]

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.[77] 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.[78] 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.[79] 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."

## 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[80]:

“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."

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

## Regulatory Status

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 (PROTECT-AF) randomized controlled trial.[12] In 2020, the Watchman FLX device (Boston Scientific) was approved by the FDA based on the single-arm, nonrandomized PINNACLE FLX study.[8] 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).[9] The Watchman and Amplatzer Amulet devices are indicated to reduce the risk of thromboembolism from the LAA in patients 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 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, 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. |

| Date | Comments |
|---|---|
| 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. |
| 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. |



**Scope**: Medical policies are systematically developed guidelines that serve as a resource for Company staff when determining coverage for specific medical procedures, drugs or devices. Coverage for medical services is subject to the limits and conditions of the member benefit plan. Members and their providers should consult the member

benefit booklet or contact a customer service representative to determine whether there are any benefit limitations applicable to this service or supply. This medical policy does not apply to Medicare Advantage.