Corporate Medical Policy

Percutaneous Left Atrial Appendage Closure Device for Stroke Prevention

File Name: percutaneous_left_atrial_appendage_closure_device_for_stroke_prevention
Origination: 4/2011
Last Review: 6/2023

Description of Procedure or Service

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

Atrial fibrillation (AF) is the most common type of irregular heartbeat, affecting at least 2.7 million people in the United States. Stroke is the most serious complication of AF. The estimated incidence of stroke in nontreated 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.

The main treatment for stroke prevention in AF is anticoagulation, which has proven efficacy. Prediction of stroke risk among patients with AF is evaluated using several factors. Two commonly used scores are the CHADS2 score (congestive heart failure, hypertension, age ≥75 years, diabetes mellitus, stroke/transient ischemic attack), which has been largely supplanted by the CHA2DS2-VASC score (CHADS2 plus vascular disease, age 65 to 74 years, and female sex). The CHA2DS2-VASC model demonstrates an advantage for discriminating the potential for stroke in lower-risk patient groups, therefore might facilitate more specific preventive strategies. Warfarin is the predominant agent in clinical use. A number of newer anticoagulant medications, including dabigatran, rivaroxaban, and apixaban, have received U.S. Food and Drug Administration (FDA) approval for stroke prevention in nonvalvular AF and have demonstrated noninferiority to warfarin in clinical trials. 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. 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 guidelines from the American College of Chest Physicians (2012) recommend that CHA2DS2-VASc be used to evaluate stroke risk, and patients initially identified as having a low stroke risk should not be given antithrombotic therapy. In addition, they recommend bleeding risk assessments be given to every patient at every patient contact and that “potentially modifiable bleeding risk factors” should be the initial focus.

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. The devices may prevent stroke by occluding the LAA and 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 transeptal puncture to enter the left atrium. Transesophageal echocardiography and fluoroscopy are used to guide the procedure. Following implantation, patients receive anticoagulation with warfarin or alternate agents for approximately 1-2 months. After this period, patients are maintained on antiplatelet agents (i.e., aspirin and/or clopidrogel) indefinitely. The Watchman FLX device is a next-generation Watchman device that is also FDA-approved for LAAC. This device based on the design of the Watchman device, is fully recapturable and repositionable, and was made to occlude a wider size range of LAA than the original Watchman device. The Amplatzer cardiac plug (St. Jude Medical), is FDA-approved for closure of atrial septal defects but not for LAA closure. A second-generation device, the Amplatzer Amulet, has been developed for the specific indication of LAAC, received FDA approval in August 2021. The Amplatzer Amulet consists of a nitinol mesh disc to seal the ostium of the LAA and a nitinol mesh distal lobe, to be positioned within the LAA. The device is preloaded within a delivery sheath. The Percutaneous LAA Transcatheter Occlusion device (ev3) has also been evaluated in research studies but has not received FDA approval. The 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. This was based on an analysis of registry data from 49,357 patients who underwent LAA closure with the Watchman device. When adjusted for multiple confounding factors, the study found women were more likely than men to experience any adverse event, major adverse events, and major bleeding. Women also had a significantly higher risk of death (adjusted odds ratio [OR], 2.01; 95% confidence interval [CI] 1.31 to 3.09) but absolute risk was low for both women and men (0.3% vs. 0.1%). In their letter, the FDA stated that they believe the benefits continue to outweigh the risks for approved LAA closure devices when used in accordance with their instructions for use.

Regulatory Status

The Watchman™ Left Atrial Appendage Closure Technology (Boston Scientific) was approved by the FDA through the premarket approval process in 2015, on the basis of the Left Atrial Appendage Versus Warfarin Therapy for Prevention of Stroke in Patients with Atrial Fibrillation randomized controlled trial. In 2020, the Watchman FLX device (Boston Scientific) was approved by the FDA based on the single-arm, nonrandomized PINNACLE FLX study. The Amplatzer™ Amulet™ Left Atrial Appendage Occluder (Abbott) received FDA approval in 2021 through the premarket approval process based on results from the Amplatzer Amulet Left Atrial Appendage Occluder Randomized Controlled Trial (Amulet IDE Trial). The Watchman and Amplatzer amulet devices are indicated to reduce the risk of thromboembolism from the LAA in patients with nonvalvular AF 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 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.

Several other devices are being evaluated for left atrial appendage occlusion, but are not approved in the U.S. for percutaneous LAAC. The Lariat® Loop Applicator device (SentreHEART) is a suture delivery system that received 510(k) marketing clearance from the FDA in 2006. The intended use is to facilitate suture placement and knot tying in surgical applications where soft tissues are being approximated or ligated with a pre-tied polyester suture. The Amplatzer Cardiac Plug device (St. Jude Medical) and WaveCrest™ (Johnson & Johnson Biosense Webster) have CE approval in Europe for left atrial appendage closure, but are not currently approved in the U.S. for this indication.

In June 2010, the AtriClip LAA Exclusion System (Atricure) was cleared for marketing by the U.S. Food and Drug Administration (FDA) through the 510(k) process (K093679). The FDA determined that this device was substantially equivalent to existing devices for occlusion of the LAA. The AtriClip has gone through numerous iterations since 2010, primarily relating to changes in the clip material composition and refinements of the clip applicator. The current FDA cleared indication is unchanged from the original 2010 indication, which states that the AtriClip is indicated for "exclusion of the LAA, performed under direct visualization, in conjunction with other cardiac surgical procedures." The FDA clearance documentation notes that direct visualization “requires that the surgeon is able to see the heart directly, with or without assistance from a camera, endoscope, etc. or other appropriate viewing technologies." As of 2022, AtriCure markets 7 different versions of the AtriClip device, whose use varies according to LAA size and type of concomitant surgical procedure.

Related policies:
Congenital Heart Defect, Repair Devices
Facility Billing Requirements

******Note: This Medical Policy is complex and technical. For questions concerning the technical language and/or specific clinical indications for its use, please consult your physician.***

Policy

The use of percutaneous left-atrial appendage closure devices for the prevention of stroke in atrial fibrillation is considered medical necessary when approved by the U.S. Food and Drug Administration (FDA).

Benefits Application

This medical policy relates only to the services or supplies described herein. Please refer to the Member's Benefit Booklet for availability of benefits. Member's benefits may vary according to benefit design; therefore member benefit language should be reviewed before applying the terms of this medical policy.

When Percutaneous Left Atrial Appendage Closure Devices are covered

The use of a device with U.S. Food and Drug Administration (FDA) approval for percutaneous left atrial appendage closure (eg, 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:

The individual must have:

- An increased risk of stroke and systemic embolism, based upon a CHADS2 score ≥2 (Congestive heart failure, Hypertension, Age > 75, Diabetes, Stroke/transient ischemia attack/thromboembolism) **or** CHA2DS2-VASc score ≥ 3 (Congestive heart failure, Hypertension, Age ≥ 65, Diabetes, Stroke/transient ischemia attack/thromboembolism, Vascular disease, Sex category – 0 for male; 1 for female); and
- A formal shared decision making interaction with an independent non-interventional physician using an evidence-based decision tool on oral anticoagulation in patients with non-valvular atrial fibrillation (NVAF) prior to LAAC. Additionally, the shared decision making interaction must be documented in the medical record; and
- 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 long-term risks of systemic anticoagulation should outweigh the risks of the device implantation.

When Percutaneous Left Atrial Appendage Closure Devices are not covered

The use of a device with FDA approval for percutaneous left atrial appendage closure (eg, the Watchman or Amplatzer Amulet) for stroke prevention in individuals who do not meet the above criteria is considered investigational.

The use of other percutaneous left atrial appendage closure devices, including the Lariat and Amplatzer Cardiac Plug devices, for prevention of stroke in individuals with atrial fibrillation is considered investigational.

The use of surgical left atrial appendage occlusion devices, including the AtriClip device, for stroke prevention in individuals with atrial fibrillation undergoing open or thorascopic cardiac procedures is considered investigational.

The use of surgical left atrial appendage occlusion devices, including the AtriClip device, for stroke prevention as a stand-alone procedure for stroke prevention in individuals with atrial fibrillation is considered investigational.

Policy Guidelines

For individuals who have atrial fibrillation (AF) who are at increased risk of embolic stroke who receive an FDA-approved percutaneous 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 2 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 2 years of follow-up, with continued benefits with the Watchman device after 4 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 5-year follow up for the 2 Watchman trials reported that the Watchman device is noninferior to warfarin on the composite outcome of stroke, systemic embolism, and cardiovascular death. Also, the Watchman was associated with lower rates of major bleeding, particularly hemorrhagic stroke, and mortality over the long term. Evidence for the Amplatzer Amulet device comes from 2 RCTs comparing the Amulet and Watchman devices, one of which was a 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.

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 4 years of follow-up, the study found LAA closure with either the Watchman or Amulet was noninferior to anticoagulants for a composite outcome that included stroke, TIA, systematic embolism, clinically significant bleeding, significant periprocedural or device-related complications, or cardiovascular mortality. Among patients 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 a meaningful 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 or Amplatzer device (eg, the 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 which compared outcomes among patients undergoing LAAC with the Lariat device with patients receiving anticoagulant or antiplatelet therapy, reported fewer thromboembolic events in the group receiving the Lariat device. Evidence from other observational studies of these devices which report high procedural success but also numerous complications. In addition, these devices do not have the U.S. Food and Drug Administration (FDA) approval for LAA closure. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals with AF at increased risk for embolic stroke undergoing LAA occlusion with an AtriClip device concomitant with open or thoracoscopic cardiac surgical procedures, the evidence includes a randomized controlled trial (RCT), a controlled observational study, and case series. Relevant outcomes are ischemic stroke, cardiac events, and mortality. Although evidence from several systematic reviews and a large (N>10,000) observational study found surgical LAA occlusion associated with a reduction in the risk of stroke without an increase in the risk of adverse events, direct evidence specifically comparing the AtriClip Left Atrial Appendage Exclusion System with anticoagulation, another surgical occlusion method, or no occlusion is limited. LAA occlusion was associated with a reduced risk of stroke versus no occlusion in the Left Atrial Appendage Occlusion Study (LAAOS) III trial, but the trial was not designed to specifically assess the net health benefit of LAA occlusion with an AtriClip device. A retrospective database study that compared the AtriClip device with no occlusion found that AtriClip placement was associated with a lower risk of ischemic stroke, which was not statistically significant, and a reduced risk of thromboembolism that was of marginal statistical significance. Large (N>100) case series of AtriClip device use with 2- to 3- years follow-up reported stroke rates ≤1% in the postoperative period and ≤2% in the long-term follow-up. Well-designed RCTs with follow-up of 1 year or more comparing the AtriClip device with anticoagulation, other surgical occlusion methods, and/or no occlusion are needed to provide adequate evidence for assessment of net health benefit. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals with AF at increased risk for embolic stroke undergoing LAA occlusion with an AtriClip device as a stand-alone procedure, the evidence includes a controlled observational study and case series. Relevant outcomes are ischemic stroke, cardiac events, and mortality. One small (N=40) industry sponsored retrospective observational study reported that use of the AtriClip device as a stand-alone procedure resulted in similar outcomes compared to percutaneous LAA occlusion. This evidence is too limited to draw definitive conclusions. Well-designed RCTs with follow-up of 1 year or more comparing stand-alone AtriClip device placement with percutaneous LAA occlusion are needed to provide adequate evidence for assessment of net health benefit. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

Billing/Coding/Physician Documentation Information

This policy may apply to the following codes. Inclusion of a code in this section does not guarantee that it will be reimbursed. For further information on reimbursement guidelines, please see Administrative Policies on the Blue Cross Blue Shield of North Carolina web site at www.bcbsnc.com. They are listed in the Category Search on the Medical Policy search page.

Applicable service codes: *33267, 33268, 33269, 33340*

BCBSNC may request medical records for determination of medical necessity. When medical records are requested, letters of support and/or explanation are often useful, but are not sufficient documentation unless all specific information needed to make a medical necessity determination is included.

Scientific Background and Reference Sources

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For Policy re-titled "Percutaneous Left Appendage Closure Device for Stroke Prevention"

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Specialty Matched Consultant Advisory Panel review 6/2021

Medical Director review 6/2021

Medical Director review 5/2022

Specialty Matched Consultant Advisory Panel review 6/2022

Medical Director review 6/2022

U.S. Food and Drug Administration. AtriClip LAA Exclusion System

AtriCure. AtriClip LAA Exclusion System

Medical Director review 8/2022

Specialty Matched Consultant Advisory Panel review 6/2023

Medical Director review 6/2023

Policy Implementation/Update Information

For policy titled "Left Atrial Appendage Closure Device for Stroke Prevention"

4/26/11 New policy implemented. Left atrial appendage closure devices for prevention of stroke in patients with atrial fibrillation are considered investigational. Notice given 4/26/11. Effective date 8/2/11. (mco)

12/30/11 Coding update. 0281T added to "Billing/Coding" section. New code is effective 1/1/2012. (mco)

For Policy re-titled "Percutaneous Left Appendage Closure Device for Stroke Prevention"

7/10/12 Specialty Matched Consultant Advisory Panel review 6/2012. References updated. Policy title and policy statements revised to include "percutaneous." Description section updated. (mco)

7/16/13 Specialty Matched Consultant Advisory Panel review 6/2013. References updated. Description section and Policy Guidelines updated. (mco)

7/15/14 Specialty Matched Consultant Advisory Panel review 6/2014. Medical Director review 6/2014. References updated. Description section and Policy Guidelines updated. No changes to Policy Statements. (mco)

8/26/14 Description section updated. Policy Guidelines updated. References updated. No changes to Policy Statement. (mco)

9/1/15 Specialty Matched Consultant Advisory Panel review 6/24/2015. Medical Director review 6/2015. Policy Statement remains unchanged. (td)

2/29/16 Description section updated. Policy Guidelines section updated. Policy intent remains unchanged. References updated. Senior Medical Director review 2/2016. (td)

7/26/16 Minor updates to Description section. Policy statement revised for FDA approved percutaneous LAA closure device, changing from investigational to medically necessary. Policy Guidelines and references updated. Specialty Matched Consultant Advisory Panel review 6/2016 Medical Director review 6/2016. (jd)

10/25/16 "When Covered" section revised to include CHADS2 and CHA2DS2-VASc scores and indicators, formal shared decision making with an independent non-interventional physician on oral anticoagulation in patients with NVAF prior to LAAC with requirement of documentation 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. Code section and References updated. Specialty Matched Consultant Advisory Panel review 9/2016. Medical Director review 9/2016. (jd)

6/30/17 Regulatory status updated. Minor revision to code section. References updated. Medical Director review 5/2017. (jd)

7/28/17 Specialty Matched Consultant Advisory Panel review 6/2017. Medical Director review 6/2017. (jd)

7/27/18 Description section, including regulatory status updated. Policy guidelines and references updated. Specialty Matched Consultant Advisory Panel review 6/2018. Medical Director review 6/2018. (jd)

7/1/19 Description section, Regulatory status, and policy guidelines updated. References updated. Specialty Matched Consultant Advisory Panel review 6/2019. Medical Director review 6/2019. (jd)

6/30/20 Specialty Matched Consultant Advisory Panel review 6/2020. Medical Director review 6/2020. (jd)

7/1/21 Specialty Matched Consultant Advisory Panel review 6/2021. Medical Director review 6/2021. (jd)

12/30/21 The following codes were added to the Billing/Coding section effective 1/1/22: 33267, 33268, 33269. (jd)

5/31/22 The following reimbursement policy was added to Related Policies section: Facility Billing Requirements. (jd)

7/12/22 Description including regulatory status updated. Added "or Amplatzer Amulet" to both the Covered and Non-Covered sections. Added ", including the Lariat and Amplatzer Cardiac Plug devices," to the second non-covered statement for clarity. No change to policy intent. Policy guidelines updated. Specialty Matched Consultant Advisory Panel review 6/2022. Medical Director review 6/2022. (jd)

9/13/22 Regulatory Status, References and Policy Guidelines updated. Added investigational statements regarding AtriClip device to Not Covered section. Medical Director review 8/2022. (tm)

6/30/23 Description, Policy Guidelines and References updated. Minor edits to the When Covered and Not Covered sections for clarity, no change to policy intent. Specialty Matched Consultant Advisory Panel review 6/2023. Medical Director review 6/2023. (tm)