MEDICAL POLICY

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MEDICAL POLICY DETAILS	
Medical Policy Title	**Percutaneous Left Atrial Appendage Closure Devices**
Policy Number	**7.01.92**
Category	**Technology Assessment**
Original Effective Date	**08/20/15**
Committee Approval Date	**10/20/16, 11/16/17, 11/15/18, 11/21/19, 11/19/20, 11/18/21, 7/21/22**
Current Effective Date	**7/21/22**
Archived Date	**N/A**
Archive Review Date	**N/A**
Product Disclaimer	• *If a product excludes coverage for a service, it is not covered, and medical policy criteria do not apply.* • *If a commercial product (including an Essential Plan or Child Health Plus product), medical policy criteria apply to the benefit.* • *If a Medicaid product covers a specific service, and there are no New York State Medicaid guidelines (eMedNY) criteria, medical policy criteria apply to the benefit.* • *If a Medicare product (including Medicare HMO-Dual Special Needs Program (DSNP) product) covers a specific service, and there is no national or local Medicare coverage decision for the service, medical policy criteria apply to the benefit.* • *If a Medicare HMO-Dual Special Needs Program (DSNP) product DOES NOT cover a specific service, please refer to the Medicaid Product coverage line.*

POLICY STATEMENT

I. Based upon our criteria and assessment of the peer-reviewed literature, the use of a device with U.S. Food and Drug Administration (FDA) approval for percutaneous left atrial appendage closure (e.g., the WATCHMAN, Amplazter Amulet) has been medically proven to be effective and, therefore, is considered **medically appropriate** for the prevention of stroke in patients with nonvalvular atrial fibrillation, when **ALL** of the following criteria are met:

   A. There is an increased risk of stroke and systemic embolism, based on CHADS2 greater than or equal to 2 or CHA2DS2-VASc score greater than or equal to 3; and
   B. Systemic anticoagulation therapy is recommended; and
   C. Long-term risks of systemic anticoagulation outweigh the risks of the device implantation. *(See Policy Guideline)*

II. Based upon our criteria and assessment of the peer-reviewed literature, the use of a device for percutaneous left atrial appendage closure is considered **investigational** when the above criteria are not met.

POLICY GUIDELINE

The balance of risks and benefits associated with implantation of the WATCHMAN device for stroke prevention, as an alternative to systemic oral anticoagulation, should be determined on an individual basis, through administration of an evidence-based decision tool (e.g., National Institute for Health and Care Excellence (NICE) Atrial fibrillation: anticoagulant options decision aid), taking into account a patient's demonstrated bleeding episodes. A formal, shared decision-making interaction between the patient and non-implanting physician(s) involved in the patient's care (primary care physician and/or primary cardiologist), resulting in a determination of the patient's suitability for short-term oral anticoagulation but inability to take long-term oral anticoagulation, must be documented in the medical record.

DESCRIPTION

Stroke is the most serious complication of atrial fibrillation (AF). The estimated incidence of stroke in untreated patients with AF is 5% per year. Stroke associated with AF is primarily embolic in nature, tends to be more severe than the typical ischemic stroke, and causes higher rates of mortality and disability. As a result, stroke prevention is one of the main goals of AF treatment. Stroke in AF occurs primarily as a result of thromboembolism from the left atrium. The lack of atrial contractions in AF leads to blood stasis in the left atrium, and this low-flow state increases the risk for thrombosis. The area of the left atrium with the lowest blood flow in AF, and, therefore, the highest risk of thrombosis, is the left atrial appendage (LAA). It has been estimated that 90% of left-atrial thrombi occur in the LAA.

The CHADS2 or the CHA2DS2-VASc are two risk stratification scores used to calculate the risk of stroke in patients with AF. The CHADS2 score assigns points for each of the following findings: congestive heart failure, hypertension, age greater than 75, diabetes, stroke/transient ischemia attack/thromboembolism. The CHA2DS2-VASc assigns points for some of the same findings (congestive heart failure, hypertension, diabetes, stroke/transient ischemia attack/thromboembolism), but with some different or additional criteria: age greater than or equal to 65, vascular disease, gender category.

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

A number of risk scores have been developed to estimate the risk of significant bleeding in patients treated with systemic anticoagulation. An example is the HAS-BLED score, which assesses the annual risk of significant bleeding in AF patients treated with warfarin. The score ranges from 0 to 9, based on a number of clinical characteristics: hypertension, abnormal renal and/or liver function, stroke, bleeding, labile international normalized ratios, advanced age (older than 65), drug and/or alcohol use. Scores of 3 or greater are considered to be associated with high risk of bleeding.

Surgical removal, or exclusion, of the LAA is often performed in patients with AF who are undergoing open heart surgery for other reasons. Percutaneous LAA closure devices have been developed as a non-pharmacologic alternative to anticoagulation for stroke prevention in AF patients. The devices may prevent stroke by occluding the LAA, thus preventing thrombus formation. Several versions of LAA occlusion devices have been developed. The WATCHMAN and WATCHMAN FLX left atrial appendage systems (Boston Scientific, Maple Grove, MN) are self-expanding, nickel titanium devices. The devices have a polyester covering and fixation barbs for attachment to the endocardium. Implantation is performed percutaneously through a catheter delivery system, utilizing venous access and transseptal puncture to enter the left atrium. Following implantation, patients are anticoagulated with warfarin or alternate agents for approximately one to two months. After this period, patients are maintained on antiplatelet agents (e.g., aspirin and/or clopidogrel) indefinitely. The Lariat Loop Applicator is a suture delivery device that is intended to close a variety of surgical wounds, in addition to LAA closure. The Cardioblate closure device, developed by Medtronic Corp., is currently being tested in clinical studies. The Amplatzer cardiac plug (St. Jude Medical, Minneapolis, MN), is FDA-approved for closure of atrial septal defects but has not received FDA approval for LAA closure. The Percutaneous Left Atrial Appendage Transcatheter Occlusion (PLAATO) system was the first device specifically developed for LAA occlusion. It consisted of a self-expanding nitinol cage with three anchors on each strut and was covered with a non-thrombogenic PTFE membrane. However, the device was withdrawn from the market in 2006 and is no longer available for clinical use.

The Amplatzer Amulet Left Atrial Appendage Occluder (LAAO) is a permanent implant that is made of a Nitinol (nickel-titanium) mesh with polyester fabric cover. The Amplatzer Amulet is placed in the patient's left atrial appendage (LAA), the device is intended to prevent blood clots formed in the LAA from entering the bloodstream and potentially causing a stroke. Amplatzer Amulet (Abbott) was FDA approved in August 2021, it is a second-generation device, developed for the specific indication of the Left Atrial Appendage Closure (LAAC).

RATIONALE

In 2014, the National Institute on Health and Care Excellence (NICE) recommended consideration of LAA occlusion, if anticoagulation is contraindicated or not tolerated.

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

WATCHMAN Devices

Boston Scientific Corporation received FDA approval for the WATCHMAN LAA closure device in March 2015. This is the only device currently FDA-approved for percutaneous closure of the LAA. The WATCHMAN device is indicated to reduce the risk of thromboembolism from the LAA in patients with non-valvular AF who: are at increased risk for stroke and systemic embolism, based on CHADS2 or CHA2DS2-VASc1 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.

The most relevant evidence on use of a WATCHMAN device for LAA closure in patients eligible for anticoagulation is derived from two industry-sponsored, randomized, controlled trials (RCTs) and a patient-level meta-analysis of those studies. This evidence suggests that the WATCHMAN is associated with an increased periprocedural ischemic stroke risk, which is balanced against a decreased hemorrhagic stroke risk. After five years of follow-up, meta-analytic results showed that the ischemic stroke risk beyond seven days did not differ between the LAA closure group and the warfarin group, and the hemorrhagic stroke risk remained significantly lower in the LAA closure group. The results showed that the WATCHMAN device is non-inferior to warfarin alone in stroke prevention among patients with nonvalvular AF. Also, patients treated with the WATCHMAN device experienced significantly lower bleeding and mortality.

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

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

A second RCT, the PREVAIL trial (Holmes et al., 2014), was conducted after the FDA's 2009 decision not to approve the WATCHMAN device to address some of the limitations of the PROTECT AF study, including its inclusion of patients with low stroke risk (CHADS2 scores of 1), high rates of adjunctive antiplatelet therapy use in both groups, and generally

poor compliance with warfarin therapy in the control group. In the PREVAIL trial, 407 subjects were randomized in a 2:1 fashion to either the WATCHMAN device or control, which consisted of either initiation or continuation of warfarin therapy with a target international normalized ratio (INR) of 2.0 to 3.0. Subjects had nonvalvular AF and required treatment for prevention of thromboembolism, based on a CHADS2 score of 2 or higher (or ≥1 with other indications for warfarin therapy based on American College of Cardiology/American Heart Association/European Society of Cardiology guidelines), and were eligible for warfarin therapy. In the WATCHMAN group, warfarin and low-dose aspirin were continued until 45 days post-procedure; if a follow-up echocardiogram at 45 days showed occlusion of the LAA, warfarin therapy could be discontinued. Subjects who discontinued warfarin were treated with aspirin and clopidogrel for six months post-device implantation, and with 325 mg aspirin indefinitely after that. Three non-inferiority primary efficacy end points were specified: (1) occurrence of ischemic or hemorrhagic stroke, cardiovascular or unexplained death, and systemic embolism (18-month rates); (2) occurrence of late ischemic stroke and systemic embolization (beyond seven days post-randomization, 18-month rates); and (3) occurrence of all-cause death, ischemic stroke, systemic embolism, or device- or procedure-related events requiring open cardiac surgery or major endovascular intervention (e.g., pseudoaneurysm repair, arteriovenous fistula repair, or other major endovascular repair) occurring within ~~7~~seven days of the procedure or by hospital discharge, whichever was later. The 18-month event rates were determined using Bayesian statistical methods to integrate data from the PROTECT-AF study. The first primary end point, the 18-month modeled RR between the device and control groups was 1.07 (95% Crl, 0.57 to 1.89). Because the upper bound of the 95% CrI was above the preset non-inferiority margin of 1.75, the non-inferiority criteria was not met. For the second primary end point of late ischemic stroke and systemic embolization, the 18-month RR between the device and control groups was 1.6 (95% Crl, 0.5 to 4.2), with an upper bound of the 95% CrI above the preset non-inferiority margin of 2.0. The rate difference between the device and control groups was 0.005 (95% Crl, -0.019 to 0.027). The upper bound of the 95% CrI was lower than the non-inferiority margin of 0.0275, so the non-inferiority criterion was met for the rate difference. For the third primary end point, major safety issues, the non-inferiority criterion was met.

The WATCHMAN FLX device received FDA approval in July of 2020 after positive 12-month results from the PINNACLE FLX clinical trial (2018), which assessed the safety and efficacy of the next-generation Boston Scientific WATCHMAN FLX Left Atrial Appendage Closure (LAAC) Device for patients with non-valvular AF (NVAF). The prospective, non-randomized PINNACLE FLX trial included 400 patients in the U.S. with NVAF who were eligible for anti-coagulation therapy to reduce the risk of stroke but had an appropriate rationale to seek a non-pharmaceutical alternative. The trial met its primary safety endpoint – defined as occurrence of a major procedure-related complication within seven days following the procedure or time of hospital discharge, whichever was later – with a low adverse event rate of 0.5 percent. The study also met its primary effectiveness endpoint, with data demonstrating a 100 percent rate of effective LAA closure at 12 months post-procedure with peri-device flow of less than 5 mm. Ninety percent of the patients showed absolutely no detectable leakage around the device at their 12-month follow-up. The clinical trial also demonstrated an implant success rate of 98.8 percent, and no patients experienced peri-procedural death, device embolization or pericardial effusion requiring cardiac surgery, all of which is favorable in the context of previous clinical studies. In addition, 96.2 percent of patients were able to discontinue oral anticoagulation following their 45-day follow-up. Secondary endpoints from the PINNACLE FLX study, including the occurrence of ischemic stroke or systemic embolism, will be reported after 24 months of patient follow-up.

AMPLATZER AMULET

The left atrial appendage (LAA) occlusion (LAAO) provides protection against thromboembolic events in high-risk, atrial fibrillation patients. There are now three percutaneous devices that are currently approved by the FDA, the Watchman devices, (Watchman and Watchman FLX) (Boston Scientific Corporation, Marlborough, MA) and the Amplatzer Ampulet LAA occlude (Abbott, Minneapolis, MN). The Amplatzer Amulet received FDA approval in August of 2021. It is a permanent implant that is placed in the patient's LAA. The device is intended to prevent clots from forming in the LAA, entering the bloodstream, and potentially causing a stroke. The device is made of a Nitinol (Nickel-titanium) mesh with polyester fabric cover.

A randomized control trial was conducted (Lakkireddy, et al., 2021) to evaluate the safety and effectiveness of the dual-seal mechanism of the Amulet LAA Occluder compared to the Watchman device (Amulet IDE trial (Amplatzer Left Atrial Appendage Occluder IDE Trial). Patients with nonvalvular atrial fibrillations at increased risk of stroke were

randomly assigned (1:1) to undergo percutaneous implantation of a LAA occlude (Amulet or Watchman device). The primary endpoints included safety, effectiveness, and the rate of LAA occlusion at 45 days. Prespecified secondary endpoints included a composite of all strokes, systemic embolism, or cardiovascular/unexplained death at 18 months, major bleeding at 18 months and superiority test of the three primary end points. A total of 1878 patients were enrolled; the Amulet occlude was noninferior to the Watchman device for primary safety end point (14.5% versus 14.7%; difference, -0.14 [95% CI, –3.42 to 3.13]; *P*<0.001 for noninferiority). Major bleeding and all-cause death were similar between groups (10.6% versus 10.0% and 3.9% versus 5.1%, respectively). Procedure-related complications were higher for the Amulet Occluder (4.5% versus 2.5%), largely related to more frequent pericardial effusion and device embolization. The Amulet Occluder was noninferior to the Watchman device for the primary effectiveness end point (2.8% versus 2.8%; difference=0.00[95% CI, –1.55 to 1.55]; *P*<0.001 for noninferiority), and the composite of stroke, systemic embolism, or cardiovascular/unexplained death (5.6% versus 7.7%, difference, -2.12 [95% CI, -4.45to 0.21]; *P*<0.001 for noninferiority). The rate of major bleeding was similar between groups (11.6% versus 12.3%; difference, -0.71 [95% CI, –3.72 to 2.31]; *P*=0.32 for superiority). LAA occlusion was higher for the Amulet occluder than for the Watchman device (98.9% versus 96.8%; difference, 2.03 [95% CI, 0.41–3.66]; *P*<0.001 for noninferiority; *P*=0.003 for superiority). The Amulet was noninferior for safety and effectiveness of stroke prevention for nonvalvular atrial fibrillation compared with the Watchman device and superior for LAA occlusion. Procedure related complications were higher with the Amulet Occluder and decreased with operator experience.

OTHER DEVICES

Other devices that are currently being investigated but are not approved in the U.S. for percutaneous closure of the LAA include the Lariat Loop Applicator device, Cardioblate closure device, Amplatzer cardiac plug, and PLAATO system. Also, the Amplatzer Amulet device (St. Jude Medical, Plymouth, MN) has received CE certification in Europe for LAA closure; in addition, on August 24, 2021, the FDA notified St. Jude Medical that premarket approval was granted.

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

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

Several studies have reported the use of the Amplatzer device in patients with a contraindication to oral anticoagulation therapy. The largest study included 100 patients with AF, a CHADS2 score of 2 or higher, and a contraindication to oral warfarin who were treated with the Amplatzer device at a single institution (Meerkin et al., 2013). All patients were treated with heparin during the procedure; they were maintained on clopidogrel for one month post-procedure, and daily aspirin indefinitely. Successful deployment occurred in all patients. There were two significant periprocedural complications, including one pericardial effusion with tamponade and ~~1~~one case of acute respiratory distress with pulmonary edema.

Wiebe and colleagues (2013) reported results of a retrospective cohort of 60 patients with NVAF who had a CHA2DS2-VASc score of at least 1 and contraindications to warfarin anticoagulation, and who underwent percutaneous LAA closure with the Amplatzer device. Contraindications to warfarin were defined as the contraindications identified on the warfarin product label, a history of severe bleeding while receiving anticoagulant therapy, and a history of bleeding tendencies in the absence of anticoagulation or blood dyscrasia, along with the inability to maintain a stable INR, a known hypersensitivity to warfarin, or a high-risk of falling. Patients received heparin during the closure procedure; they were maintained on clopidogrel for three months post-procedure, and daily aspirin indefinitely. Device implantation was successful in 95% of patients. Over a median follow-up of 1.8 years, no patients experienced a stroke. The rate of major bleeding complications was 1.9% during the year of follow-up.

CODES

- *Eligibility for reimbursement is based upon the benefits set forth in the member's subscriber contract.*
- *CODES MAY NOT BE COVERED UNDER ALL CIRCUMSTANCES. PLEASE READ THE POLICY AND GUIDELINES STATEMENTS CAREFULLY.*
- *Codes may not be all inclusive as the AMA and CMS code updates may occur more frequently than policy updates.*

CPT Codes

Code	Description
33340	Percutaneous transcatheter closure of the left atrial appendage with endocardial implant, including fluoroscopy, transseptal puncture, catheter placement(s), left atrial angiography, left atrial appendage angiography, when performed, and radiological supervision and interpretation

HCPCS Codes

Code	Description
No specific codes	

ICD10 Codes

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

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*Key Article

KEY WORDS

Amplatzer Amulet, Amplatzer cardiac plug, Lariat, PLAATO, WATCHMAN.

CMS COVERAGE FOR MEDICARE PRODUCT MEMBERS

There is currently a National Coverage Determination (NCD) for percutaneous left atrial appendage closure (LAAC) (20.34). Please refer to the following NCD website for Medicare Members: https://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?NCDId=367&ncdver=1&CoverageSelection=Both&ArticleType=All&PolicyType=Final&s=New+York+-+Upstate&CptHcpcsCode=36514&bc=gAAAABAAAAAAAA%3d%3d&