MEDICAL POLICY

Excellus

MEDICAL POLICY DETAILS	
Medical Policy Title	**PERCUTANEOUS LEFT ATRIAL APPENDAGE CLOSURE DEVICES**
Policy Number	**7.01.92**
Category	**Technology assessment**
Effective Date	**08/20/15**
Revised Date	**10/20/16, 11/16/17, 11/15/18**
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 product) or a Medicaid product covers a specific service, medical policy criteria apply to the benefit.* • *If a Medicare 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.*

POLICY STATEMENT

I. Based on our criteria and assessment of 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) has been medically proven to be effective *and therefore, 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 I.).

II. Based on our criteria and assessment of 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 GUIDELINES

I. 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 made on an individual basis as determined by demonstrated bleeding episodes OR through administration of an evidence-based decision tool (e.g. National Institute for Health and Care Excellence (NICE) Atrial fibrillation: anticoagulant options decision aid). A formal shared decision making interaction between the patient and nonimplanting physician(s) who are involved in the care of the patient (primary care physician or primary cardiologist) resulting in suitability for short-term oral anticoagulation but inability to take long-term oral anticoagulation must be documented in the medical record.

The Federal Employee Health Benefit Program (FEHBP/FEP) requires that procedures, devices or laboratory tests approved by the U.S. Food and Drug Administration (FDA) may not be considered investigational and thus these procedures, devices or laboratory tests may be assessed only on the basis of their medical necessity.

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 atrial fibrillation. 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 the same categories with some additional criteria: Congestive heart failure, Hypertension, Age greater than or equal to 65, Diabetes, Stroke/transient ischemia attack/thromboembolism, Vascular disease, Sex 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 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. 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 patients with AF treated with warfarin. The score ranges from 0-9 based on a number of clinical characteristics: Hypertension, Abnormal renal and/or liver function, Stroke, Bleeding, Labile international normalized ratios, Elderly (older than 65), Drugs and/or alcohol. 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. The devices may prevent stroke by occluding the LAA, thus preventing thrombus formation. Several versions of LAA occlusion devices have been developed. The Watchman™ left atrial appendage system (Boston Scientific, Maple Grove, MN) 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, utilizing venous access and transseptal puncture to enter the left atrium. Following implantation, patients are anticoagulated with warfarin or alternate agents for approximately 1 to 2 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 left atrial appendage 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 device. The Percutaneous LAA Transcatheter Occlusion device (eV3, Plymouth, MN) has also been evaluated in research studies but has not received FDA approval.
The PLAATO (Percutaneous Left Atrial Appendage Transcatheter Occlusion) system was the first device specifically developed for left atrial appendage (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. The device is no longer available for clinical use after withdrawal from the market in 2006.

RATIONALE

Boston Scientific Corporation received FDA approval for the WATCHMAN left atrial appendage closure device in March 2015. This is the only currently FDA approved device for percutaneous closure of the LAA. The WATCHMAN Device is indicated to reduce the risk of thromboembolism from the left atrial appendage (LAA) in patients with non-valvular atrial fibrillation 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.

Other devices 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 the PLAATO system. Also, the Amplatzer Amulet® device (St. Jude Medical, Plymouth, MN) has a CE approval in Europe for left atrial appendage closure, but is not currently approved in the U.S. for any indication.

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.

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

WATCHMAN™ Device

The most relevant evidence on use of the Watchman device for LAAC in patients eligible for anticoagulation is derived from 2 industry-sponsored 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 5 years of follow-up, meta-analytic results showed that the ischemic stroke risk beyond 7 days did not differ between the LAAC group and the warfarin group and that the hemorrhagic stroke risk remained significantly lower in the LAAC group. The results showed that the Watchman device is noninferior 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 noninferiority 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 [GI] 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 excess in 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 anticoagulation was 0.71, and this met noninferiority criteria with a confidence of greater than 99%. Complications were more common in the Watchman group, with an estimated rate of 5.6%/year in the Watchman group compared with 3.6%/year in the warfarin group.

A second RCT, the PREVAIL trial (Holmes, et al. 2014), was conducted after the 2009 FDA decision of non-approval on 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 device group, warfarin and low-dose aspirin were continued until 45 days postprocedure; 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 6 months postdevice implantation and with 325 mg aspirin indefinitely after that. Three noninferiority 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 7 days postrandomization, 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 (eg, pseudoaneurysm repair, arteriovenous fistula repair, or other major endovascular repair) occurring within 7 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 noninferiority margin of 1.75, the noninferiority criteria were not met. For the second primary end point of late ischemic stroke and systemic embolization, the 18-month RR between the device and control groups was 1.6 (95% Crl, 0.5 to 4.2), with an upper bound of the 95% CrI above the preset noninferiority 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 noninferiority margin of 0.0275, so the noninferiority criterion was met for the rate difference. For the third primary end point, major safety issues, the noninferiority criterion was met.

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 3 access-related complications, 2 cases of severe pericarditis postoperatively, 1 late pericardial effusion, and 2 cases of unexplained sudden death. There were 2 late strokes, which the authors did not attribute to an embolic source. At 1-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,(16) 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 1 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 left atrial 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). Longer term adverse outcomes occurred in 7% of patients, including 2 strokes, 1 peripheral embolization, and 4 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 1 month postprocedure and daily aspirin indefinitely. Successful deployment occurred in all patients. There were 2 significant periprocedural complications, including 1 pericardial effusion with tamponade and 1 case of acute respiratory distress with pulmonary edema.

Wiebe and colleagues (2013) reported results of a retrospective cohort of 60 patients with nonvalvular AF who had a CHA2DS2-VASc score of at least 1 and contraindications to warfarin anticoagulation who underwent percutaneous LAA closure with the Amplatzer device. Contraindications to warfarin included contraindications as defined in the warfarin product label, a history of severe bleeding while receiving anticoagulant therapy as well as a history of bleeding tendencies in the absence of anticoagulation or blood dyscrasia, along with patients who were unable to maintain a stable INR and those with a known hypersensitivity to warfarin or a high-risk of falling who were also included. Patients received heparin during the closure procedure; they were maintained on clopidogrel for 3 months postprocedure 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% 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-I48.2	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&