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

Policy Number: 2.02.26  Last Review: 6/2014
Origination: 1/2012  Next Review: 12/2014

Policy
Blue Cross and Blue Shield of Kansas City (Blue KC) will not provide coverage for percutaneous left-atrial appendage closure devices for stroke prevention in atrial fibrillation. This is considered investigational.

When Policy Topic is covered
Not Applicable

When Policy Topic is not covered
The use of percutaneous left-atrial appendage closure devices for the prevention of stroke in atrial fibrillation is considered investigational.

Description of Procedure or Service
Stroke prevention in atrial fibrillation is an important consideration. Treatment with anticoagulant medications is the most common approach to stroke prevention. Most embolic strokes originate from the left atrial appendage; therefore, occlusion of the left atrial appendage may offer a nonpharmacologic alternative to anticoagulant medications for the prevention of stroke in patients with AF. Multiple percutaneously-deployed devices are being investigated for left atrial appendage closure.

Background
Stroke is the most serious complication of atrial fibrillation. The estimated incidence of stroke in non-treated patients with atrial fibrillation is 5% per year. Stroke associated with atrial fibrillation 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 atrial fibrillation treatment.

Stroke occurs primarily as a result of thromboembolism from the left atrium. The lack of atrial contractions in atrial fibrillation 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 atrial fibrillation, 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. The risk for stroke among patients with AF is stratified on the basis of several factors. A commonly used score, the CHADS2 score, assigns 1 point each for the presence of heart failure, hypertension, age 75 years or older, diabetes, or prior stroke or transient ischemic attack (TIA). The CHA2DS2-VASc score includes sex, more age categories, and the presence of vascular disease, in addition to the risk factors used in the CHADS2 score. Warfarin is the predominant agent in clinical use. A number of newer anticoagulant medications, including dabigatran, rivaroxaban, and apixaban, have recently 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. Guidelines from the American College of Chest Physicians recommend the use of oral anticoagulation for patients with AF who are at high risk of stroke (ie, CHADS2 score of 2 or greater), with more individualized choice of antithrombotic therapy in patients with lower stroke risk.(1)

Surgical removal, or exclusion, of the LAA is often performed in patients with atrial fibrillation who are undergoing open heart surgery for other reasons. Percutaneous LAA closure devices have been developed as a nonpharmacologic alternative to anticoagulation for stroke prevention in atrial fibrillation. 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 1-2 months. After this period, patients are maintained on antiplatelet agents (i.e., aspirin and/or clopidogrel) indefinitely. 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 (PLAATO) device (eV3, Plymouth, MN) has also been evaluated in research studies but has not received FDA approval.

Regulatory Status
There are currently no percutaneous LAA closure devices with FDA approval for that indication. In December 2013, an FDA advisory panel voted in favor of premarket approval clearance for the Watchman™ Left Atrial Appendage Closure Therapy.(2) However, in June 2014, FDA determined that the device will be required to undergo a third panel review before it would consider approval. The Watchman™ device was originally considered for FDA approval in 2009 based on the results of the Percutaneous Closure of the Left Atrial Appendage Versus Warfarin Therapy for Prevention of Stroke in Patients with Atrial Fibrillation (PROTECT-AF) randomized controlled trial (RCT). While the FDA advisory panel for this topic voted in favor of approval, FDA did not grant final approval after concluding that further studies of efficacy and safety were necessary.

At least two other devices, referred to earlier, have been studied for LAA occlusion, but are not approved in the U.S. for percutaneous closure of the LAA. The Lariat® Loop Applicator device (SentreHEART, Inc, Redwood City, CA) is a suture delivery system that received 510(k) marketing clearance from 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 pretied polyester suture. 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.

Rationale
This policy was created in 2011 and updated periodically with literature review. The most recent update with literature review covers the period of January 2013 through June 5, 2014.

Literature review

The evidence on the efficacy of left atrial appendage (LAA) closure devices consists of numerous case series of various occlusion devices, 1 randomized controlled trial (RCT) of the Watchman™ device that compared LAA closure with warfarin anticoagulation for which results have been published, and 1 RCT of the Watchman™ device that has been presented to the FDA advisory panel. Evidence on each
different device will be reviewed separately, because the devices are not similar in design, and each may have its own unique considerations.

**Watchman device**

The review of the evidence related to the efficacy of the Watchman device is based, in part, on a Blue Cross Blue Shield Association (BCBSA) TEC Assessment developed in June 2014, which evaluated use of the Watchman device for patients who were eligible and ineligible for anticoagulation therapy and determined that it does not meet Technology Evaluation Criteria.(3) Although the Watchman device and other LAA closure devices would ideally represent an alternative to oral anticoagulation for the prevention of stroke in patients with AF, during the postimplantation period, the device may be associated with increased thrombogenicity and, therefore, anticoagulation is used during the periprocedural period. Most studies that have evaluated the Watchman device have included patients who are eligible for anticoagulation.

**Patients who are eligible for anticoagulation.** Two RCTs have evaluated the Watchman device for stroke prevention in patients with atrial fibrillation (AF).

The single RCT published is the PROTECT-AF study, (4) 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% CI, 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. (5) 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.

Alli et al reported quality-of-life parameters, as measured by change in scores on the Short-Form 12 Health Survey from baseline to 12 months of follow up, for a subset of 547 subjects in the PROTECT AF study.(6) For the subset of PROTECT AF subjects included in the present analysis, at baseline, control group subjects had a higher mean CHADS2 score (2.4 vs 2.2; p=0.0517) and were more likely to have a history of coronary artery disease (49.5% vs 39.6%; p=0.0275). For subjects in the
Watchman group, the total physical score improved in 34.9% and was unchanged in 29.9%; for those in the warfarin group, the total physical score improved in 24.7% and was unchanged in 31.7% (p=0.01).

A second RCT, the PREVAIL trial, was conducted after the 2009 FDA decision 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. Results from the PREVAIL trial have been presented in FDA documentation, but not in peer-reviewed form.(2) In the PREVAIL trial, 461 subjects enrolled at 41 sites 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 2.0-3.0. Subjects had nonvalvular AF and required treatment for prevention of thromboembolism based on a CHADS2 score of 2 or higher (or 1 or higher 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% CrI, 0.57 to 1.89). Because the upper bound of the 95% credible interval 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% CrI, 0.5 to 4.2), with an upper bound of the 95% credible interval above the preset noninferiority margin of 2.0. The rate difference between the device and control groups was 0.0053 (95% CrI, -0.0190 to 0.0273). The upper bound of the 95% credible interval 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. At the time of the FDA decision, only 28% of PREVAIL subjects had actually reached 18-month follow-up.

In addition to these RCTs, a number of case series have reported on outcomes on the Watchman device. A number of small published case series are primarily intended to establish safety and feasibility of the device. (7-11) A larger case series of 143 patients from Europe was published in 2011. (9) This series reported that successful implantation was achieved in 96% (137/143) of patients and that serious complications occurred in 7.0% (10/143). Complications included stroke (n=3), device embolization (n=2), and pericardial effusion (n=5). Another larger series was reported by Reddy et al, (10) primarily focusing on the adverse event rate from a registry of 460 patients who received the Watchman device. Serious pericardial effusion occurred in 2.2% of patients, and there were no deaths or periprocedural strokes reported. Matsuo et al reported results from a case series of 179 patients who underwent LAA closure at a single center, most (n=172) of whom received a Watchman device.(12) Device deployment was successful in 98.9% of patients. The overall complication rate was 11.2%; major complications occurred in 3.3% (tamponade in 2 cases; possible transient ischemic attack [TIA] in 1 case; and device dislocation in 3 cases). At 45-day follow up, 99.4% of patients (164/166) had closure of the LAA.

Patients who are not eligible for anticoagulation.
The PROTECT AF and PREVAIL studies included only patients who were candidates for oral anticoagulation therapy. As such, uncertainty remains about the role of the Watchman device in patients with AF who have absolute contraindications to oral anticoagulants. Reddy et al conducted a multicenter, prospective, nonrandomized trial to evaluate the safety and efficacy of LAA closure with the Watchman device in patients with nonvalvular AF with a CHADS2 score 1 or higher who were considered ineligible for warfarin. Postimplantation, patients received 6 months of clopidogrel or ticlopidine and lifelong aspirin therapy. Thirteen patients (8.7%) had a procedure- or device-related serious adverse event, most commonly pericardial effusion (3 patients). Over a mean 14.4 months of follow-up, all-cause stroke or systemic embolism occurred in 4 patients.

Chun et al compared the Watchman™ device with the Amplatzer cardiac plug among patients with nonvalvular AF, who were at high risk for stroke and had a contraindication to or were not willing to accept oral anticoagulants. Eighty patients were randomized to LAA occlusion with the Watchman™ or the Amplatzer device. After device implantation, either preexisting oral anticoagulation therapy or dual platelet inhibition with aspirin and clopidogrel was continued for 6 weeks. A follow-up transesophageal echocardiogram was performed at 6 weeks postprocedure; if a device-related thrombus had formed, patients received intensive antithrombotic therapy for 6 weeks. Aspirin was continued indefinitely for all patients. The primary end point of successful device implantation occurred in 98% of patients. There were no statistically significant differences in procedure time, fluoroscopy time, or major safety events between the 2 groups. At a median 364 days of follow-up, there were no cases of stroke/TIA or other bleeding complications.

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 et al 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 of 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 1 procedural complication in which the snare was unable to be removed and needed to be retrieved by thoracoscopy.

In 2013, Stone et al reported outcomes for 27 patients with AF, a high stroke risk (CHADS2 score of 2 or higher), and contraindications or intolerance to anticoagulation who underwent percutaneous LAA ligation with the Lariat device. Acute procedural success was 92.6%; periprocedural complications included 3 cases of pericarditis and 1 periprocedural stroke which was associated with no long-term disability. A follow-up transesophageal echo was performed in 22 patients at an average of 45 days postprocedure, which demonstrated successful LAA exclusion in all 22. Follow-up was for an average of 4 months, during which time 1 stroke and no deaths occurred.

Massumi et al. reported on 21 patients with AF and contraindications to anticoagulation. A total of 20/21 patients had successful atrial closure, which was documented by echocardiography to be intact at a mean follow-up of 96 days. No patients had a stroke during a mean follow-up of approximately 1 year. There were complications reported in 5/21 patients. One patient had right ventricular perforation and tamponade requiring surgical intervention. One patient developed pleuro-pericarditis that required multiple drainage procedures. Three additional patients developed pericarditis within 30 days of the procedure.

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, (19) 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 of 86 patients from Portugal, (20) 37 patients from Italy, (21) 35 patients from Spain, (22) 21 patients from Poland, (23) and 20 patients from China. (24) 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. (25) 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 et al 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. (26) 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.

Urena et al. reported results from a similar cohort of 52 patients with nonvalvular AF who had a CHA2DS2- VASc score of at least 2 and contraindication to oral anticoagulation therapy who underwent percutaneous LAA closure with the Amplatzer device. (27) Device implantation was successful in all but 1 patient. There were no periprocedural strokes or death. Over the follow-up period (mean 20 months), rates of death, stroke, and systemic embolism were 5.8 (3/52), 1.9% (1/52), and 0%, respectively.

Other smaller case series of patients with contraindication to oral anticoagulation include studies by Danna et al, (28) which included 37 patients and reported a 1-year stroke rate of 2.94%, and Horstmann et al, (29) which included 20 patients and reported no episodes of strokes over a mean follow-up of 13.6 months.

PLAATO device

The available evidence on outcomes following use of the PLAATO device for stroke prevention in AF comes from case series and cohort studies. Bayard et al reported on 180 patients with nonrheumatic AF and a contraindication to warfarin and who were treated with the Percutaneous Left Atrial Appendage Transcatheter Occlusion (PLAATO) device. (30) Placement was successful in 90% of patients. Two patients died within 24 hours of the procedure (1.1%), and 6 patients had cardiac tamponade (3.3%), with 2 requiring surgical drainage. Other case reports and small case series report complications, including multiple reports of thrombus formation at the site of device placement. (31, 32)

Ongoing clinical trials
There are currently a number of additional ongoing clinical trials of LAA closure devices. (33) Of studies listed online at ClinicalTrials.gov, there are at least 4 RCTs listed as of February 2014:

- NCT01628068. ELIGIBLE (Efficacy of Left atrial Appendage Closure After GastroIntestinal Bleeding) study. This study randomizes patients with a history of GI bleed with nonvalvular to left atrial occlusion with the Amplatzer device or usual care with anticoagulation. Enrollment is planned for 120 subjects; the expected completion date is July 2014.
- NCT01363895. Interventional Strategies in Treatment of Atrial Fibrillation: Percutaneous Closure of the Left Atrial Appendage Versus Catheter Ablation. This is a study that randomizes 120 patients with AF to left atrial closure with the Watchman™ device or catheter ablation. Estimated completion date is November 2013.
- NCT01118299. AMPLATZER Cardiac Plug Clinical Trial. This trial randomizes 3000 patients with AF to left atrial occlusion with the Amplatzer® cardiac plug versus optimal medical care. Estimated completion date is June 2017.
- NCT02039167. Left Atrial Appendage Occlusion vs. Usual Care in Patients With Atrial Fibrillation and Severe Chronic Kidney Disease (WatchAFIB). This study randomizes patients with severe chronic kidney disease with paroxysmal, persistent, or permanent nonvalvular AF to LAA occlusion with the Watchman® device or to usual care. Enrollment is planned for 300 subjects; the expected completion date is June 2017.

**Summary**

Left atrial appendage (LAA) occlusion devices are nonpharmacologic alternatives to anticoagulation for stroke prevention in patients with atrial fibrillation. Currently, there are no devices that have FDA-approval for this indication in the U.S., but at least 3 different devices have been evaluated for this purpose. Case series have demonstrated that these devices can be successfully implanted percutaneously in most patients. Complications such as pericardial effusion and tamponade are reported in available studies at a rate of 2% to 5%.

One published RCT compared the Watchman™ device with warfarin and reported noninferiority on a composite outcome of stroke, cardiovascular/unexplained death, or systemic embolism after 2 years of follow-up. There were a higher number of complications in the LAA closure group, primarily due to early complications associated with the device placement. Data from another RCT have been presented to the FDA advisory panel but have not yet been published in the peer reviewed literature.

For the Lariat, PLAATO, and Amplatzer devices, there were no controlled trials identified. Case series of these devices report high procedural success but also numerous complications.

Given the lack of FDA approval, the limited published data regarding impact on net health outcome from controlled trials, and the potential for complications, left atrial appendage closure devices are considered investigational.

**Practice Guidelines and Position Statements**

The American College of Chest Physicians has evidence-based clinical best practice guidelines on the use of antithrombotic therapy for prevention of stroke in AF.(1) In relation to the use of LAA closure devices, the guidelines state: “At this time, we make no formal recommendations regarding LAA closure devices, pending more definitive research in this field.”

In 2014, the American College of Cardiology, the American Heart Association, and the Heart Rhythm Society issued guidelines on the management of patients with AF.(34) These guidelines recommend that surgical excision of the LAA may be considered in patients undergoing cardiac surgery (Class IIB recommendation; Level of evidence: C), but make no specific recommendations regarding percutaneous LAA closure.
LAA closure devices are not preventive services and are therefore not included in the U.S. Preventive Task Force Recommendations for preventive services.

References

**Billing Coding/Physician Documentation Information**

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<td>0281T</td>
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**Additional Policy Key Words**

N/A

**Policy Implementation/Update Information**

1/1/12  New policy; considered investigational.
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