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 CAP Review: 6/2020
Next CAP Review: 6/2021
Last Review: 6/2020

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). There is one left atrial appendage device (the Watchman device) with 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 models 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. 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 (2012) recommend the use of oral anticoagulation for patients with AF who are at high risk of stroke (ie, CHADS2 score greater than or equal to 2, with more individualized choice of antithrombotic therapy in patients with lower stroke risk.

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 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, but does not have current FDA approval. 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.

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.

This device is indicated to reduce the risk of thromboembolism from the left atrial appendage (LAA) in patients with nonvalvular atrial fibrillation 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 warfarin; and
- Have an appropriate rationale to seek a nonpharmacologic alternative to warfarin, taking into account the safety and effectiveness of the device compared to warfarin.

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 Amulet® 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.

Related policies:
Congenital Heart Defect, Repair Devices

Percutaneous Left Atrial Appendage Closure Device for Stroke Prevention

******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) may be considered medically necessary for the prevention of stroke in patients with atrial fibrillation when the following criteria are met:

The patient 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) for stroke prevention in patients who do not meet the above criteria is considered investigational.

The use of other percutaneous left atrial appendage closure devices for prevention of stroke in patients with atrial fibrillation is considered investigational.

Policy Guidelines

The evidence for the use of the Watchman percutaneous LAAC device for stroke prevention in patients with atrial fibrillation (AF) includes 2 randomized controlled trials (RCTs) and meta-analyses of these trials. Relevant outcomes are overall survival, morbid events, and treatment-related morbidity. The most relevant evidence comes from 2 industry-sponsored RCTs that compared 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 trials reported that the Watchman device is noninferior to warfarin on the composite outcome of stroke, systemic embolism, and cardiovascular death. The Watchman was associated with lower rates in major bleeding, particularly hemorrhagic stroke, and mortality over the long term. The evidence also indicates that the Watchman device is efficacious in preventing stroke in the subset of patients with AF who are at increased risk for embolic stroke. 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.

The evidence for the use of a percutaneous LAAC device other than the Watchman (eg, the Lariat and Amplatzer devices) for stroke prevention in patients with AF includes several nonrandomized comparator studies and uncontrolled case series. 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. Two nonrandomized studies compared the Amplatzer cardiac plug with the Amplatzer amulet. While the amulet may be technically easier to implant, clinical outcomes were similar between the two groups. The remaining evidence consists of case series 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.

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: *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

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

Reddy VY, Holmes D, Doshi SK et al. Safety of percutaneous left atrial appendage closure: results from the Watchman Left Atrial Appendage System for embolic protection in patients with AF (PROTECT-AF) clinical trial and the Continued Access Registry. Circulation 2011; 123(4):417-24.

Bayard YL, Omran H, Neuzil P et al. PLAATO (Percutaneous Left Atrial Appendage Transcatheter Occlusion) for prevention of cardioembolic stroke in non-anticoagulation eligible atrial fibrillation patients: results from the European PLAATO study. EuroIntervention 2010; 6(2):220-6.

Fuller CJ, Reisman M. Stroke prevention in atrial fibrillation: atrial appendage closure. Curr Cardiol Rep 2011; 13(2):159-66.

National Institutes of Health (NIH). AMPLATZER Cardiac Plug Clinical Trial. Clinical trial #NCT01118299. Last reviewed May 18, 2012 from http://www.clinicaltrials.gov/ct2/show/NCT01118299?term=amplatzer&rank=9

National Institutes of Health (NIH). ASA Plavix Feasibility Study With WATCHMAN Left Atrial Appendage Closure Technology (ASAP). Clinical trial #NCT00851578. Last reviewed on May 18, 2012 from http://www.clinicaltrials.gov/ct2/show/NCT00851578

National Institutes of Health (NIH). Evaluation of the Next Generation WATCHMAN LAA Closure Technology in Non-Valvular AF Patients (EVOLVE). Clinical trial #NCT01196897. Last reviewed on May 18, 2012 from http://www.clinicaltrials.gov/ct2/show/NCT01196897?term=watchman&rank=3

National Institutes of Health (NIH). Evaluation of the Cardioblate Closure Device in Facilitating Occlusion of the Left Atrial Appendage. Clinical trial #NCT00841529. Last reviewed on May 18, 2012 from http://www.clinicaltrials.gov/ct2/show/NCT00841529?term=cardioblate&rank=1

BCBSA Medical Policy Reference Manual [Electronic Version]. 2.02.26, 4/14/11

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

BCBSA Medical Policy Reference Manual [Electronic Version]. 2.02.26, 3/8/12

Specialty Matched Consultant Advisory Panel review 6/2012

Streb W, Szymala M, Kukulski T et al. Percutaneous closure of the left atrial appendage using the Amplatzer Cardiac Plug in patients with atrial fibrillation: evaluation of safety and feasibility. Kardiol Pol 2013; 71(1):8-16. Retrieved from http://ojs.kardiologiapolska.pl/kp/article/view/7606

Freixa X, Chan JL, Tzikas A, Garceau P, Basmadjian A, Ibrahim R. The Amplatzer™ Cardiac Plug 2 for left atrial appendage occlusion: novel features and first-in-man experience. EuroIntervention. 2013 Jan 22;8(9):1094-8. Retrieved from http://www.pcronline.com/eurointervention/56th_issue/167/

Montenegro MJ, Quintella EF, Damonte A et al. Percutaneous occlusion of left atrial appendage with the Amplatzer Cardiac PlugTM in atrial fibrillation. Arq Bras Cardiol 2012; 98(2):143-50. Retrieved from http://www.scielo.br/scielo.php?script=sci_arttext&pid=S0066-782X2012000200007&lng=en&nrm=iso&tlng=en

BCBSA Medical Policy Reference Manual [Electronic Version]. 2.02.26, 3/14/13

Specialty Matched Consultant Advisory Panel review 6/2013

Reddy VY, Doshi SK, Sievert H, Buchbinder M, Neuzil P, Huber K, Halperin JL, Holmes D; PROTECT AF Investigators. Percutaneous left atrial appendage closure for stroke prophylaxis in patients with atrial fibrillation: 2.3-Year Follow-up of the PROTECT AF (Watchman Left Atrial Appendage System for Embolic Protection in Patients with Atrial Fibrillation) Trial. Circulation. 2013 Feb 12;127(6):720-9. http://circ.ahajournals.org/content/127/6/720.long

FDA Executive Summary December 11, 2013 meeting of the Circulatory System Devices PanelP130013 Boston Scientific WATCHMAN® Left Atrial Appendage Closure Therapy. http://www.fda.gov/downloads/advisorycommittees/committeesmeetingmaterials/medicaldevices/medicaldevicesadvisorycommittee/circulatorysystemdevicespanel/ucm377356.pdf

National Institutes of Health (NIH). Evaluation of the WATCHMAN LAA Closure Device in Patients With Atrial Fibrillation Versus Long Term Warfarin Therapy (PREVAIL). Clinical trial NCT01182441. http://clinicaltrials.gov/ct2/show/NCT01182441?term=PREVAIL&rank=3

Specialty Matched Consultant Advisory Panel review 6/2014

Medical Director review 6/2014

You JJ, Singer DE, Howard PA et al. Antithrombotic therapy for atrial fibrillation: Antithrombotic Therapy and Prevention of Thrombosis, 9th ed: American College of Chest Physicians Evidence-Based Clinical Practice Guidelines. Chest 2012; 141(2 Suppl):e531S-75S. http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3278056/

Blue Cross and Blue Shield Association. Technology Evaluation Center (TEC). Percutaneous left atrial appendage closure therapy for prevention of stroke. TEC Assessments 2014; Volume 29.

Matsuo Y, Sandri M, Mangner N et al. Interventional Closure of the Left Atrial Appendage for Stroke Prevention. Circ J 2014; 78(3):619-24. https://www.jstage.jst.go.jp/article/circj/78/3/78_CJ-13-0828/_pdf

Reddy VY, Möbius-Winkler S, Miller MA et al. Left Atrial Appendage Closure With the Watchman Device in Patients With a Contraindication for Oral AnticoagulationThe ASAP Study (ASA Plavix Feasibility Study With Watchman Left Atrial Appendage Closure Technology). J Am Coll Cardiol 2013; 61(25):2551-56. http://www.sciencedirect.com/science/article/pii/S0735109713014150

BCBSA Medical Policy Reference Manual [Electronic Version]. 2.02.26, 7/10/14

Specialty Matched Consultant Advisory Panel review 6/2015

Medical Director review 6/2015

BCBSA Medical Policy Reference Manual [Electronic Version]. 2.02.26, 10/15/15

Senior Medical Director review 2/2016

Briceno DF, Villablanca P, Cyrille N, et al. Left Atrial Appendage Occlusion Device and Novel Oral Anticoagulants Versus Warfarin for Stroke Prevention in Nonvalvular Atrial Fibrillation: Systematic Review and Meta-Analysis of Randomized Controlled Trials. Circ Arrhythm Electrophysiol. Oct 2015;8(5):1057-1064. PMID 26226997

Holmes DR, Jr., Doshi SK, Kar S, et al. Left atrial appendage closure as an alternative to warfarin for stroke prevention in atrial fibrillation: a patient-level meta-analysis. J Am Coll Cardiol. Jun 23 2015;65(24):2614-2623. PMID 26088300

Boersma LV, Schmidt B, Betts TR, et al. Implant success and safety of left atrial appendage closure with the WATCHMAN device: peri-procedural outcomes from the EWOLUTION registry. Eur Heart J. Jan 27 2016. PMID 26822918

BCBSA Medical Policy Reference Manual [Electronic Version]. 2.02.26, 5/2016

Medical Director review 5/2016

Specialty Matched Consultant Advisory Panel review 6/2016

Medical Director review 6/2016

The Centers for Medicare and Medicaid, National Coverage Determination NCD 20.34 Percutaneous Left Atrial Appendage Closure (LAAC), Effective date 2/8/16 with Implementation date 10/3/16,

Accessed at https://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?NCDId=367&ncdver=1&DocID=20.34+&bc=gAAAABAAAAAAAA%3d%3d& August 25, 2016.

2014 AHA/ACC/HRS Guideline for the Management of Patients With Atrial Fibrillation: Executive Summary, Clinical Practice Guideline; Vol.64, No. 21, ISSN 0735-1097

American College of Cardiology Foundation, American Heart Association, European Society of Cardiology, et al. Management of patients with atrial fibrillation (compilation of 2006 ACCF/AHA/ESC and 2011 ACCF/AHA/HRS recommendations): a report of the American College of Cardiology/American Heart Association Task Force on practice guidelines. Circulation 2013; 127:1916.

Camm AJ, Lip GY, De Caterina R, et al. 2012 focused update of the ESC Guidelines for the management of atrial fibrillation: an update of the 2010 ESC Guidelines for the management of atrial fibrillation--developed with the special contribution of the European Heart Rhythm Association. Europace 2012; 14:1385.

David R. Holmes, MD; Dhanunjaya R. Lakkireddy, MD; Richard P. Whitlock, MD, PhD‡; Ron Waksman, MD; Michael J. Mack, MD; J Am Coll Cardiol. 2014;63(4):291-298. doi:10.1016/j.jacc.2013.08.1631

Specialty Matched Consultant Advisory Panel review 9/2016

Medical Director review 9/2016

BCBSA Medical Policy Reference Manual [Electronic Version]. 2.02.26, 5/2017

Medical Director review 5/2017.

Specialty Matched Consultant Advisory Panel review 6/2017

Medical Director review 6/2017

BCBSA Medical Policy Reference Manual [Electronic Version]. 2.02.26, 5/2018

Specialty Matched Consultant Advisory Panel review 6/2018

Medical Director review 6/2018

BCBSA Medical Policy Reference Manual [Electronic Version]. 2.02.26, 6/2019

Specialty Matched Consultant Advisory Panel review 6/2019

Medical Director review 6/2019

Specialty Matched Consultant Advisory Panel review 6/2020

Medical Director review 6/2020

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)