Percutaneous Left Atrial Appendage Closure Device for Stroke Prevention

Description of Procedure or Service

Stroke prevention in 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 for this purpose. Multiple percutaneously deployed devices are being investigated for left atrial appendage closure (LAAC). There is 1 left atrial appendage (LAA) occlusion device with approval from the U.S. Food and Drug Administration (FDA) for stroke prevention in patients with AF, the Watchman device.

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 in atrial fibrillation 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. Prediction of stroke risk among patients with AF has relied mainly on models of clinical variables. Evaluation and comparison of these models indicate relatively poor performance, with inability to predict central nervous system events. In a study that followed 79,884 patients for approximately 4 years, these models show only a modest discriminatory ability for risk prediction. Two commonly used models are the CHADS2 (congestive heart failure, hypertension, age ≥75 years, diabetes mellitus, stroke/transient ischemic attack) score, which has been largely supplanted by the CHA2DS2-VASC (CHADS2 plus vascular disease, age 65 to 74 years, and female sex) score. 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 recommend the use of oral anticoagulation for patients with AF.
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who are at high risk of stroke (i.e., 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 atrial fibrillation 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 atrial fibrillation. The devices may prevent stroke by occluding the LAA and thus preventing thrombus formation.

Several versions of LAA occlusion devices have been developed. 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. 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 clopidrogel) 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 (Medtronic) is currently being tested in clinical studies. 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. 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.

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 (PROTECT-AF) 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 closure of the left atrial appendage. 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® (Coherex Medical) 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
Catheter Ablation as a Treatment for Atrial Fibrillation

***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.
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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 (LAAC, 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 LAA closure 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, morbidity 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
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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. When it is determined on an individualized basis that 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 left atrial appendage (LAA) closure device other than the Watchman (eg, the Lariat, PLAATO, and Amplatzer devices) for stroke prevention in patients with AF includes uncontrolled case series. Relevant outcomes are overall survival, morbid events, and treatment-related morbidity. Case series of these devices 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”


Percutaneous Left Atrial Appendage Closure Device for Stroke Prevention


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


Specialty Matched Consultant Advisory Panel review 6/2012


Specialty Matched Consultant Advisory Panel review 6/2013


Specialty Matched Consultant Advisory Panel review 6/2014

Medical Director review 6/2014

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Based Clinical Practice Guidelines. Chest 2012; 141(2 Suppl):e531S-75S.  
http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3278056/  


Specialty Matched Consultant Advisory Panel review 6/2015  
Medical Director review 6/2015  

Senior Medical Director review 2/2016  


Medical Director review 5/2016  
Medical Director review 6/2016  


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
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Medical Director review 9/2016


Medical Director review 5/2017.

Specialty Matched Consultant Advisory Panel review 6/2017

Medical Director review 6/2017


Specialty Matched Consultant Advisory Panel review 6/2018

Medical Director review 6/2018

Policy Implementation/Update Information

For policy titled “Left Atrial Appendage Closure Device for Stroke Prevention”


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)

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


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)


Medical policy is not an authorization, certification, explanation of benefits or a contract. Benefits and eligibility are determined before medical guidelines and payment guidelines are applied. Benefits are determined by the group contract and subscriber certificate that is in effect at the time services are rendered. This document is solely provided for informational purposes only and is based on research of current medical literature and review of common medical practices in the treatment and diagnosis of disease. Medical practices and knowledge are constantly changing and BCBSNC reserves the right to review and revise its medical policies periodically.