

## Corporate Medical Policy

### Left Atrial Appendage Closure Device for Stroke Prevention

<b>File Name:</b>	left_atrial_appendage_closure_device_for_stroke_prevention
<b>Origination:</b>	4/2011
<b>Last CAP Review:</b>	n/a
<b>Next CAP Review:</b>	6/2012
<b>Last Review:</b>	4/2011

#### Description of Procedure or Service

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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 atrial fibrillation is anticoagulation, which has proven efficacy. Warfarin is the predominant agent in clinical use. Dabigatran (Pradaxa®) has recently received U.S. Food and Drug Administration (FDA) approval for this indication and has demonstrated non-inferiority to warfarin in clinical trials. While anticoagulation is effective for stroke prevention, there is an increased risk of bleeding. Also, warfarin requires frequent monitoring and adjustments as well as lifestyle changes. Dabigatran does not require monitoring. However, unlike warfarin, the antithrombotic effects of Dabigatran are not reversible with any currently available hemostatic drugs.

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 the devices have been developed. The WATCHMAN® left atrial appendage system 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 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 clopidogrel) indefinitely. The Cardioblate® closure device is currently being tested in clinical studies. The Amplatzer® septal closure device is FDA-approved for closure of atrial septal defects. This device has also been used as a LAA closure device.

#### Regulatory Status

There are currently no LAA closure devices with FDA approval. The WATCHMAN® device was

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considered for FDA approval in 2009 based on the results of the PROTECT-AF randomized controlled trial. While the FDA advisory panel for this topic voted in favor of approval, the FDA did not grant final approval after concluding that further studies of efficacy and safety were necessary.

## **Related policies:**

Congenital Heart Defect, Repair Devices  
Transcatheter Ablation of Arrhythmogenic Foci in the Pulmonary Vein  
Maze Procedure for Atrial Fibrillation or Flutter

**\*\*\*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**

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**The use of left-atrial appendage closure devices for the prevention of stroke in atrial fibrillation is considered investigational. BCBSNC does not provide coverage for investigational services or procedures.**

## **Benefits Application**

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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 Left Atrial Appendage Closure Devices are covered**

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Not Applicable

## **When Left Atrial Appendage Closure Devices are not covered**

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

## **Policy Guidelines**

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LAA occlusion devices are non-pharmacologic alternatives to anticoagulation for patients with atrial fibrillation. Currently, there are no devices that have FDA-approval for this indication. 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 2-5%. Periprocedural stroke has been reported uncommonly. One randomized, controlled trial compared the WATCHMAN® device to warfarin, and reported non-inferiority 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. Longer term outcomes past 2 years have not been reported.

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## Billing/Coding/Physician Documentation Information

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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](http://www.bcbsnc.com). They are listed in the Category Search on the Medical Policy search page.

*Applicable service codes: 0281T*

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

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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. Retrieved on April 5, 2011 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. Retrieved on April 5, 2011 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. Retrieved on April 5, 2011 from <http://www.clinicaltrials.gov/ct2/show/NCT01196897?term=watchman&rank=3>

National Institutes of Health (NIH). Evaluation of the Cardioblade Closure Device in Facilitating Occlusion of the Left Atrial Appendage. Clinical trial #NCT00841529. Retrieved on April 5, 2011 from <http://www.clinicaltrials.gov/ct2/show/NCT00841529?term=cardioblade&rank=1>

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

## Policy Implementation/Update Information

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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

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1/1/2012. (mco)

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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.