**Medical Coverage Policy |** Percutaneous Left Atrial Appendage Closure Devices for Stroke Prevention in Atrial Fibrillation

**EFFECTIVE DATE:** 02|01|2019
**POLICY LAST UPDATED:** 09|04|2018

## OVERVIEW

Stroke prevention in atrial fibrillation (AF) is an important goal of treatment. Most embolic strokes originate from the left arterial appendage (LAA). Treatment with anticoagulant medications is the most common approach to stroke prevention. The Watchman™ device was approved by the U.S. Food and Drug Administration (FDA) for stroke prevention in patients with AF, and may offer a non-pharmacologic alternative to anticoagulant medications for the prevention of stroke in patients with AF.

## MEDICAL CRITERIA

**BlueCHiP for Medicare**
Not applicable.

**Commercial Products**
The use of a device with FDA approval for percutaneous left atrial appendage closure (e.g., the Watchman) may be considered **medically necessary** for the prevention of stroke in patients with atrial fibrillation when the following criteria is met:

- There is an increased risk of stroke and systemic embolism based on CHADS2 score, **or** CHA2DS2-VASc score and;
- Systemic anticoagulation therapy is recommended, and;
- The long-term risks of systemic anticoagulation outweigh the risks of the device implantation

## PRIOR AUTHORIZATION

**BlueCHiP for Medicare**
Not applicable.

**Commercial Products**
Prior authorization is recommended and obtained via the online tool for participating providers. See Related Policies section.

## POLICY STATEMENT

**BlueCHiP for Medicare**
Percutaneous left atrial appendage colure approved by the U.S. Food and Drug Administration (FDA) may be considered medically necessary for patients enrolled in a Centers for Medicare and Medicaid Services (CMS) approved clinical trial. Refer to Related Policy section.

**Note:** Blue Cross & Blue Shield of Rhode Island (BCBSRI) must follow Centers for Medicare and Medicaid Services (CMS) guidelines, such as national coverage determinations or local coverage determinations for all BlueCHiP for Medicare policies. Therefore, BlueCHiP for Medicare policies may differ from Commercial products. In some instances, benefits for BlueCHiP for Medicare may be greater than what is allowed by the CMS.

**Commercial Products**
Percutaneous left atrial appendage closure is considered medically necessary when the criteria above is met.

The use of other percutaneous left atrial appendage closure devices, including but not limited to the Lariat, ; and Amplatzer, for stroke prevention in patients with atrial fibrillation is considered not medically necessary because these devices do not have FDA approval for LAA closure. In addition, the evidence is insufficient to determine the effects of the technology on health outcomes.

## COVERAGE

Benefits may vary between groups and contracts. Please refer to the appropriate Benefit Booklet, Evidence of Coverage or Subscriber Agreement for applicable surgery benefits/coverage.

## BACKGROUND

Stroke is the most serious complication of atrial fibrillation (AF). The estimated incidence of stroke in nontreated patients with AF is 5% per year. Stroke associated with AF is primarily embolic, tends to be more severe than the typical ischemic stroke, and causes higher rates of mortality and disability. As a result, stroke prevention is a main goal 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. The risk for stroke among patients with AF is evaluated using several factors. Two commonly used scores, the CHADS2 score and the CHADS2-VASc score are described below in Table 1. 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, it carries 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) have recommended the use of oral anticoagulation for patients with AF who are at high risk of stroke (ie, CHADS2 score ≥2), with more individualized choice of antithrombotic therapy in patients with lower stroke risk.

**Table 1. $CHADS_2$ and $CHADS_2$-VASc Scores to Predict Ischemic Stroke Risk in Patients With Atrial Fibrillation**

| Letter | Clinical Characteristics | Points Awarded |
|---|---|---|
| C | Congestive heart failure (signs/symptoms of heart failure confirmed with objective evidence of cardiac dysfunction) | 1 |
| H | Hypertension (resting blood pressure >140/90 mmHg on at least 2 occasions or current antihypertensive pharmacologic treatment) | 1 |
| A | Age ≥75 y | 2 |
| D | Diabetes (fasting glucose >125 mg/dL or treatment with oral hypoglycemic agent and/or insulin) | 1 |
| S | Stroke or transient ischemic attack (includes any history of cerebral ischemia) | 2 |
| V | Vascular disease (prior myocardial infarction, peripheral arterial disease, or aortic plaque) | 1 |
| A | Age 65-74 y | 1 |
| Sc | Sex category of female (female sex confers higher risk) | 1 |

Bleeding is the primary risk associated with systemic anticoagulation. Risk scores have been developed to estimate the risk of significant bleeding in patients treated with systemic anticoagulation, such as the HAS-BLED score, which has been validated to assess the annual risk of significant bleeding in patients with AF treated with warfarin.

The score ranges from 0 to 9, based on clinical characteristics, including the presence of hypertension, renal and liver function, history of stroke, bleeding, labile international normalized ratios, age, and drug/alcohol

use. Scores of 3 or greater are considered to be associated with high risk of bleeding, potentially signaling the need for closer monitoring of patients for adverse risks, closer monitoring of international normalized ratios, or differential dose selections of oral anticoagulants or aspirin.

Surgical removal, or exclusion, of the LAA is often performed in patients with AF who are undergoing open heart surgery for other reasons. Percutaneous left atrial appendage closure (LAAC) 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) 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 transseptal puncture to enter the left atrium. Following implantation, patients receive anticoagulation with warfarin or alternative agents for approximately 1 to 2 months. After this period, patients are maintained on antiplatelet agents (ie, aspirin and/or clopidogrel) indefinitely. The Lariat Loop Applicator is a suture delivery device intended to close a variety of surgical wounds in addition to LAAC. 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 LAAC. 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.

The optimal study design for evaluating the efficacy of percutaneous LAAC for the prevention of stroke in AF is a randomized controlled trial that includes clinically relevant measures of health outcomes. The rate of ischemic stroke during follow-up is the primary outcome of interest, along with rates of systemic embolization, cardiac events, bleeding complications, and death. For the LAAC devices, the appropriate comparison group could be oral anticoagulation, no therapy (for patients who have a prohibitive risk for oral anticoagulation), or open surgical repair.

Although the Watchman device and other LAAC 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 evaluating the Watchman device have included patients who are eligible for anticoagulation.

In 2002, the PLAATO system (ev3 Endovascular) was the first device to be approved by FDA for LAA occlusion. The device was discontinued in 2007 for commercial reasons, and intellectual property was sold to manufacturers of the Watchman system.

In 2015, the Watchman™ Left Atrial Appendage Closure Technology (Boston Scientific) was approved by FDA through the premarket approval process by the Left Atrial Appendage Versus Warfarin Therapy for Prevention of Stroke in Patients with Atrial Fibrillation (PROTECT AF) randomized controlled trial.

## CODING

**BlueCHiP for Medicare**

The following codes may be allowed as part of a CMS approved clinical study:

**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

**Note:** If you are treating a BlueCHiP for Medicare member as part of a CMS approved study, please follow the procedures for correct billing and coding of services found in the policy for Clinical Trials BlueCHiP for Medicare.

Claims for services rendered as part of a CMS approved clinical study must be billed with an appropriate modifier:
**Modifier Q0** – Investigational clinical service provided in a clinical research study that is in an approved research study (Medicare claims filed without the Q0 modifier will deny as not medically necessary)
**Modifier Q1** – Routine clinical service provided in a clinical research study that is in an approved clinical research study

**Commercial Products**
The following code is medically necessary when the criteria above has been met

**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

## RELATED POLICIES
Clinical Trials BlueCHiP for Medicare
BlueCHiP for Medicare National and Local Coverage Determinations
Prior Authorization via Web-Based Tool for Procedures

## PUBLISHED
Provider Update, November 2018
Provider Update, July 2017
Provider Update, May 2016

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