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

EFFECTIVE DATE: 07|01|2016
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OVERVIEW

Stroke prevention in atrial fibrillation (AF) is an important goal of treatment. Most emoblic 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 nonpharmacologic alternative to anticoagulant medications for the prevention of stroke in patients with AF.

MEDICAL CRITERIA

BlueCHiP for Medicare and 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 ≥2, or;
- CHA2DS2-VASc score of ≥2 and;
- Systemic anticoagulation therapy is recommended, and;
- The long-term risks of systemic anticoagulation outweigh the risks of the device implantation of the HAS-BLED score of 3 or greater.

PRIOR AUTHORIZATION

BlueCHiP for Medicare and Commercial Products

Prior authorization is recommended and obtained via the online tool for participating providers.

POLICY STATEMENT

BlueCHiP for Medicare and Commercial Products

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

The use of a device with FDA approval for percutaneous left atrial appendage closure (e.g., the Watchman™) for stroke prevention in patients who do not meet the above criteria is considered not medically necessary because there is insufficient peer-reviewed scientific literature that demonstrates that the service is effective.

The use of other percutaneous left atrial appendage closure devices, including but not limited to the Lariat, PLAATO, 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/contracts. Please refer to the appropriate Evidence of Coverage, Subscriber Agreement, or Benefit Booklet for surgery benefit/coverage.

BACKGROUND

Stroke prevention in atrial fibrillation (AF) is an important goal of treatment. 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 non-pharmacologic 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. There is 1 left atrial appendage (LAA) occlusion device with approval from the FDA for stroke prevention in patients with AF, the Watchman device.

Clinical input was obtained to identify specific criteria for determining when the Watchman would be associated with clinical benefit. Results of clinical input generally supported the use of the Watchman device in patients who have an increased risk of stroke or systemic embolization but have long-term risks associated with oral anticoagulation that are determined, on an individual basis, to outweigh the short term risk of Watchman device implantation.

The balance of risks and benefits associated with implantation of the Watchman device for stroke prevention, as an alternative to systemic anticoagulation with warfarin, must be made on an individual basis.

Bleeding is the primary risk associated with systemic anticoagulation. A number of risk scores have been developed to estimate the risk of significant bleeding in patients treated with systemic anticoagulation. An example is the HAS-BLED score, which has validated to assess the annual risk of significant bleeding in patients with AF treated with warfarin (Pisters et al, 2010). The score ranges from 0 to 9, based on a number of clinical characteristics (see Table PG1).

Stroke is the most serious complication of AF. The estimated incidence of stroke in non-treated 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. 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. The CHADS2-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 FDA approval for stroke prevention in nonvalvular AF and have 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. 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 (i.e., CHADS2 score ≥2), with more individualized choice of antithrombotic therapy in patients with lower stroke risk.

Bleeding is the primary risk associated with systemic anticoagulation. A number of risk scores have been developed to estimate the risk of significant bleeding in patients treated with systemic anticoagulation. An example is the HAS-BLED score, which has 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 a number of clinical characteristics, including the presence of hypertension, renal and liver function, history of stroke, bleeding, labile international normalized ratios (INRs), 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 the patient for adverse risks, closer monitoring of INRs, or differential dose selections of oral anticoagulants or aspirin.

Table PG1: Clinical Components of the HAS-BLED Bleeding Risk Score (Pisters et al, 2010)
Letter Clinical Characteristic Points Awarded

Letter	Clinical Characteristic	Points Awarded
H	Hypertension	1
A	Abnormal renal and liver function (1 point each)	1 or 2
S	Stroke	1
B	Bleeding	1
L	Labile INRs*	1
E	Elderly (>65)	1
D	Drugs or alcohol (1 point each)	1 or 2

*INR International normalized ratio

Patients with scores of 3, 4, and 5 have been reported to have a risk of major bleeding of 3.74/100 patient years, 8.70/100 patient years, and 12.5/100 patient years, respectively. Scores of 3 or greater are considered to be associated with high risk of bleeding, potentially signaling the need for closer monitoring of the patient for adverse risks, closer monitoring of international normalized ratio, 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 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, thus preventing thrombus formation.

The evidence for the use of the Watchman device for stroke prevention in patients with AF who are candidates for oral anticoagulation includes two randomized controlled trials (RCTs) and a patient-level meta-analysis 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. One trial reported non-inferiority on a composite outcome of stroke, cardiovascular/unexplained death, or systemic embolism after two years of follow-up, with continued benefits with the Watchman after 4 years of follow-up. The second trial did not demonstrate non-inferiority for the same composite outcome, but did demonstrate non-inferiority of the Watchman device to warfarin for late ischemic stroke and systemic embolization. A patient-level meta-analysis of the two trials suggested that the Watchman is associated with a periprocedural risk of ischemic stroke but a lower risk of hemorrhagic stroke over the long term. The published evidence is sufficient to determine that the Watchman device is efficacious in preventing stroke for patients with AF who are eligible to receive systemic anticoagulation. 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 qualitatively that the technology results in a meaningful improvement in the net health outcome.

The evidence for the use of LAA closure devices other than the Watchman (e.g., 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 FDA approval for LAA closure. The evidence is insufficient to determine the effects of the technology on health outcomes.

CODING

BlueCHiP for Medicare and **Commercial Products**

The following code is medically necessary when the criteria above has been met:

0281T Percutaneous transcatheter closure of the left atrial appendage with implant, including fluoroscopy, trans-septal puncture, catheter placement(s), left atrial angiography, left atrial appendage angiography, radiological supervision and interpretation

RELATED POLICIES

Not applicable

PUBLISHED

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