

## Clinical Policy: Percutaneous Left Atrial Appendage Closure Device for Stroke Prevention

Reference Number: CP.MP.147

Last Review Date: 05/19

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See [Important Reminder](#) at the end of this policy for important regulatory and legal information.

### Description

Atrial fibrillation (AF) is the most commonly encountered sustained tachyarrhythmia and is associated with a 5-fold increased risk of stroke, and stroke risk increases with age.<sup>1</sup> Among patients with non-valvular AF, the vast majority of thrombus material is located within or involves the left atrial appendage (LAA). Most patients with atrial fibrillation should receive anticoagulant therapy to reduce the risk of systemic embolization. However, not all individuals are candidates for this therapy. LAA occlusion devices have been investigated as an alternative to pharmacological therapy to reduce the risk of stroke in these individuals.

### Policy/Criteria

- I. It is the policy of health plans affiliated with Centene Corporation<sup>®</sup> that the WATCHMAN<sup>™</sup> LAA Closure Technology for occlusion of the LAA is **medically necessary** to reduce the risk of stroke in adults with non-valvular AF when both of the following criteria are met:
  - A. There is an increased risk for stroke and systemic embolism based on CHADS2 or CHA2DS2-VASc scores and long-term anticoagulation therapy is recommended; and
  - B. Failure of and/or contraindications to long-term oral anticoagulants such as warfarin, factor Xa inhibitors, and direct thrombin inhibitors (e.g., allergic reactions, severe liver disease, recent trauma or surgery, severe high blood pressure, active bleeding, inability to obtain regular INR, etc.).
- II. It is the policy of health plans affiliated with Centene Corporation that all other percutaneous devices for occlusion of the LAA to reduce the risk of stroke in adults with non-valvular atrial fibrillation (other than the WATCHMAN LAA Closure Technology noted above), are considered **investigational**. There is a paucity of evidence regarding the long-term safety and efficacy of these devices and at this time, no other percutaneous device is FDA approved for this indication.

### Background

The individualized assessment of the risk-benefit balance is central to decision making regarding pharmacotherapy for stroke reduction in AF. To estimate stroke risk, the ACC/American Heart Association/HRS Guideline for the Management of Patients with Atrial Fibrillation recommends the use of the CHA2DS2-VASc point score [Congestive heart failure, Hypertension, Age  $\geq 75$  years (doubled), Diabetes mellitus, prior Stroke, transient ischemic attack, or thromboembolism (doubled), Vascular disease, Age 65 to 74 years, Sex category), which provides an estimate of the potential benefits of therapy. Per the guideline, oral anticoagulation is a class I recommendation for patients with prior stroke, transient ischemic attack (TIA), or a CHA2DS2-VASc score  $\geq 2$  (estimated annual stroke risk of 2.2%) in the context of shared decision making, including a discussion of risks of stroke and bleeding, and the patient's preferences.<sup>2</sup>

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Some patients with AF, whose stroke risk profiles would favor anticoagulation, have relative or absolute contraindications to anticoagulation. Others are unable or unwilling to adhere to long-term anticoagulation therapy. As a result, a number of percutaneous techniques that mechanically prevent embolization of LAA thrombi, often referred to as LAA exclusion procedures, have been investigated as an alternative to pharmacological therapy to reduce the risk of stroke. The percutaneous devices include two broad categories: endocardial plug devices to occlude the ostium of the LAA and epicardial LAA ligation procedures to exclude the LAA. At this time, only the WATCHMAN LAA Closure Technology (Boston Scientific Corporation) has been evaluated in randomized controlled trials compared with the current standard of care. This device has received approval by the Food and Drug Administration (FDA) as an alternative to warfarin for stroke prevention.

The WATCHMAN device is deployed percutaneously via transseptal puncture and has a polyethylene membrane that covers a self-expanding nitinol cage with barbs to anchor the device in the LAA. The early findings for the WATCHMAN device suggest noninferiority to warfarin for the composite endpoint of stroke, systemic embolism, and cardiovascular death; however, early adverse events occur in approximately 10% of patients, including pericardial bleeding. Longer-term follow-up of the WATCHMAN device at 1588 patient-years suggests noninferiority of this device to warfarin.<sup>3</sup> A subsequent registry study demonstrated that the WATCHMAN device achieved noninferiority in patients who could not receive warfarin.<sup>4</sup> Quality of life was assessed in a subset of patients (361 device and 186 warfarin patients) enrolled in the PROTECT AF (Percutaneous Closure of the Left Atrial Appendage Versus Warfarin Therapy for Prevention of Stroke in Patients With Atrial Fibrillation) trial at baseline and 12 months. It was reported that patients with non-valvular AF at risk for stroke, treated with left atrial appendage closure, have favorable QOL changes at 12 months versus patients treated with warfarin.<sup>5</sup>

The available evidence suggests the Watchman device may be potentially beneficial for stroke prevention in adult patients with non-valvular AF at increased risk of stroke and systemic embolism. However, there is uncertainty about whether the benefit outweighs possible harms, given the potential for device-related complications or mortality.<sup>22</sup> Percutaneous LAA closure is associated with a measurable risk of serious procedure-/device-related complications (e.g., major bleeding, pericardial effusion, stroke, device embolization, cardiac perforation or tamponade) with reported mortality rates ranging from 0% to 4%.<sup>22</sup>

The LARIAT device (SentreHEART) has FDA approval 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 FDA has not evaluated the use of the LARIAT Suture Delivery Device for LAA closure to reduce the risk of stroke in atrial fibrillation patients. In fact, the FDA has alerted health care providers and patients of reports of patient deaths and other serious adverse events associated with the use of the LARIAT Suture Delivery Device for this off label indication.

The FDA-approved AtriClip LAA Exclusion System is indicated for the occlusion of the heart's LAA, performed under direct visualization and in conjunction with other cardiac surgical procedures. Direct visualization, in this context, requires that the surgeon is able to see the heart directly, with or without assistance from a camera, endoscope, etc., or other appropriate viewing

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technologies. The American Heart Association/American College of Cardiology/ Heart Rhythm Society (AHA/ACC/HRS) concludes that the current data on LA occlusion at the time of concomitant cardiac surgery reveal a lack of clear consensus because of the inconsistency of techniques used for surgical excision, the highly variable rates of successful LAA occlusion, and the unknown impact of LAA occlusion on future thromboembolic events.<sup>1</sup> Per the AHA/ACC/HRS, surgical excision of the LAA may be considered in patients undergoing cardiac surgery. (Iib recommendation- usefulness/efficacy is less well established.)

Various other devices continue to be investigated and some have European Conformity (CE) approval in Europe for LAA closure but they do not have FDA approval in the US. Some examples include Amplatzer cardiac plug, redesigned as the Amplatzer Amulet (St. Jude Medical), WaveCrest (Coherex Medical), LAMBRE (Lifetech Scientific Corp), Occlutech LAA Occluder (Occlutech International AB), and the Cardia Ultrasept LAA Occluder (Cardia).

#### *National Institute for Health and Clinical Excellence (NICE)*

Current evidence suggests that percutaneous occlusion of the LAA is efficacious in reducing the risk of thromboembolic complications associated with nonvalvular AF. With regard to safety, there is a risk of life-threatening complications from the procedure, but the incidence of these is low. Therefore, this procedure may be used, provided that normal arrangements are in place for clinical governance, consent and audit.<sup>7</sup>

#### *European Society of Cardiology*

Guidelines for the Management of Atrial Fibrillation states LAA occlusion may be considered for stroke prevention in patients with AF and contraindications for long-term anticoagulant treatment. (Class Iib recommendation-usefulness/efficacy is less well established by evidence/opinion.)<sup>9</sup>

#### *American Heart Association/American College of Cardiology/ Heart Rhythm Society*

The latest guideline on the management of patients with atrial fibrillation (2014) briefly addresses percutaneous approaches to occlude the LAA, but does not include recommendations for the use of these devices. At the time of the development of the guideline, no percutaneous LAA closure device had an FDA-approval labeled for the indication of stroke prevention.<sup>1</sup>

### **Coding Implications**

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CPT® Codes	Description
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

HCPCS Codes	Description
N/A	

#### ICD-10-CM Diagnosis Codes that Support Coverage Criteria

ICD-10-CM Code	Description
I48.1	Persistent atrial fibrillation
I48.2	Chronic atrial fibrillation
I48.91	Unspecified atrial fibrillation

Reviews, Revisions, and Approvals	Date	Approval Date
Policy adopted from Health Net NMP 376, Left Atrial Appendage Devices	06/17	07/17
Clarified in I.A and I.B that the anticoagulation therapy recommended is for “long-term” use. Updated background information to include possible complication associated with the device. Revised information under section “AHA/ACC/HRS” for clarification purposes. References reviewed and updated.	05/18	05/18
References reviewed and updated. Coding reviewed.	04/19	05/19

#### References

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**Important Reminder**

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. “Health Plan” means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan’s affiliates, as applicable.

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for the medical advice and treatment of members. This clinical policy is not intended to recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

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**Note: For Medicaid members,** when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.

**Note: For Medicare members,** to ensure consistency with the Medicare National Coverage Determinations (NCD) and Local Coverage Determinations (LCD), all applicable NCDs, LCDs, and Medicare Coverage Articles should be reviewed prior to applying the criteria set forth in this clinical policy. Refer to the CMS website at <http://www.cms.gov> for additional information.

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