Policy: Percutaneous Left Atrial Appendage Closure Device for Stroke Prevention

Reference Number: PA.CP.MP.147
Effective Date: 01/18 Coding Implications
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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.[1] 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 Pennsylvania Health and Wellness® (PHW) that the WATCHMAN™ 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. Contraindications or unacceptable high risk of bleeding from long-term oral anticoagulants including, but not limited to:

1. Thrombocytopenia or known coagulation defect associated with bleeding;
2. Recurrent bleeding, including gastrointestinal, genitourinary, respiratory;
3. Prior severe bleeding, including intracranial hemorrhage;
4. Combined use of dual antiplatelet and anticoagulant therapy;
5. Poor compliance or intolerance with anticoagulant therapy;
6. High risk of the patient falling or prior falls resulting in injury;
7. Allergic reactions;
8. Severe liver disease;
9. Recent trauma or surgery;
10. Severe high blood pressure;
11. Inability to obtain regular international normalized ratios.

Note: Warfarin may be required for at least six weeks after implantation of the Watchman device.

II. It is the policy of PHW that there is a paucity of evidence regarding the long-term safety and efficacy of 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). 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 around 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 ≥75 years (doubled), Diabetes mellitus, prior Stroke, transient ischemic attack, or thromboembolism (doubled), Vascular disease, Age 65 to74 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 ≥ 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.[2]

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.[3] A subsequent registry study demonstrated that the WATCHMAN device achieved noninferiority in patients who could not receive warfarin.[4] Quality of life was assessed in a subset of patients (361device 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 nonvalvular AF at risk for stroke, treated with left atrial appendage closure, have favorable QOL changes at 12 months versus patients treated with warfarin. [5]

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.22 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%. [22]

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 pretied 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 technologies. The American Heart Association/American College of Cardiology/ Heart Rhythm Society (AHA/ACC/HRS) concludes 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.[1] 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.[7]

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.) [9]

American Heart Association/American College of Cardiology/ Heart Rhythm Society
The latest guideline on the management of patients with atrial fibrillation (2014) does not include recommendations for the use of LAA occlusion devices due to the lack of adequate data and the absence of an FDA-approved LAA closure device labeled for the indication of stroke prevention at the time of the development of the guideline.[1]

Coding Implications
This clinical policy references Current Procedural Terminology (CPT®). CPT® is a registered trademark of the American Medical Association. All CPT codes and descriptions are copyrighted

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
I48.11-148.19	Persistent atrial fibrillation
I48.20-148.21	Chronic atrial fibrillation
I48.91	Unspecified atrial fibrillation

Reviews, Revisions, and Approvals	Date	Approval Date
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.	06/18	
References reviewed and updated. Coding reviewed.	10/19	
References reviewed and updated. I48.1 updated to I48.11-I48.19 and I48.2 updated to I48.20-I48.21	10/2020	12/2020
Replaced "investigational" in II with "there is a paucity of evidence regarding the long-term safety and efficacy of all other percutaneous devices for occlusion of the LAA …" References reviewed and updated. Verbiage edits to I.B, adding contraindications of 1.-11, in addition to the note regarding Warfarin. Annual Review completed, References reviewed/revised, and specialist reviewed.	7/2021	9/7/2021

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