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

Reference Number: LA.CP.MP.147 Coding Implications
Date of Last Revision: 7~~1~~/22 Revision Log

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.[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~~AF should receive anticoagulant therapy to reduce the risk of systemic embolization~~.~~, ~~H~~however, not all individuals are candidates for this therapy. LAA occlusion devices have been researched~~investigated~~ as an alternative to pharmacological therapy to reduce the risk of stroke in these individuals.

Policy/Criteria

I. It is the policy of Louisiana Healthcare Connections that Federal Drug Administration (FDA) approved percutaneous devices~~the~~ (i.e. WATCHMAN™, WATCHMAN FLX™, and Amplatzer™ Amulet™) for occlusion of the left atrial appendage (LAA) ~~Closure Technology for occlusion of the LAA~~ is **medically necessary** to reduce the risk of stroke in adults with non-valvular atrial fibrillation (AF) when both of the following criteria are met:

A. There is an increased risk for stroke and systemic embolism based on $CHADS_2$~~2~~ or CHA_2~~2~~DS_2~~2~~-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 or Watchman FLX device.

II. It is the policy of Louisiana Healthcare Connections that current research does not support the use of percutaneous devices other than those noted above for occlusion of the LAA to reduce the risk of stroke in adults with non-valvular AF. There is a paucity of evidence regarding the long-term safety and efficacy of all other percutaneous devices for occlusion of the LAA, and at this time, no other devices are FDA approved for this indication. ~~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 regarding pharmacotherapy for stroke reduction in atrial fibrillation (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 CHA_2~~2~~DS_2~~2~~-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 CHA_2~~2~~DS_2~~2~~-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 left atrial appendage (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.~~
Currently, the WATCHMAN, WATCHMAN FLX, and the Amplatzer Amulet are the only FDA-approved percutaneous LAA closure devices.

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 non-valvular AF at risk for stroke, treated with left atrial appendage closure, have favorable quality of life~~QOL~~ changes at 12 months versus patients treated with warfarin. [5]

The PREVAIL study was mandated by the US FDA to further evaluate the safety profile and confirm the efficacy of the WATCHMAN device for regulatory approval. This study randomly assigned 407 patients in a 2:1 ratio to WATCHMAN or warfarin. Results from the five-year outcomes of the PREVAIL trial and the PROTECT AF trial demonstrated that LAA closure with the WATCHMAN device provided stroke prevention in nonvalvular AF that was comparable to warfarin and included additional reductions in major bleeding and mortality.[22]

The newer-generation WATCHMAN FLX is FDA approved and is widely replacing the WATCHMAN device in most centers.[22] The WATCHMAN FLX comes in five sizes with a slightly broader range of dimensions than the WATCHMAN. This device has a distal rounded edge and double row stabilizing anchors, which improves the safety of the procedure.[22,26] A single-arm prospective registry of 400 patients, the PINNACLE FLX study, concluded that LAA closure with the WATCHMAN FLX device was associated with a low incidence of adverse events and a high incidence of anatomic closure.[22,26]

The second-generation Amplatzer Cardiac Plug device, the Amulet, received FDA approval in 2021, and includes design advances such as larger lobe size for occluding larger appendages and more stabilizing wires, which improves device stability. A key difference in the Amulet device is the possibility for patients to be discharged without oral anticoagulation immediately after the device has been implanted.[27] A multicenter registry report including 1,088 patients showed 99% procedural success with 3.2% of patients having major adverse events.[22] The Amulet IDE trial included 1,878 patients with AF who were randomly assigned to receive either the Amulet or WATCHMAN percutaneous LAA occlusion device. Follow up at 18 months showed similar results between the devices with a 2.8% rate of ischemic stroke or systemic embolism.
~~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 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 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.[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 is a 2019 update of the 2014 AHA/ACC/HRS guidelines. This update addresses percutaneous approaches to occlude the LAA and has a new recommendation that percutaneous LAA occlusion may be considered in patients with AF at increased risk of stroke who have contraindications to long-term anticoagulation. FDA approval of the WATCHMAN and clinical trial data necessitated this recommendation.[1] ~~(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.[1]~~

Coding Implications
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any codes does not guarantee coverage. Providers should reference the most up-to-date sources of professional coding guidance prior to the submission of claims for reimbursement of covered services.

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	Revision Date	Approval Date
Converted corporate to local policy.	08/15/2020	
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.	1/22	1/22
Annual Review. Updated criteria I and criteria II to include all FDA approved percutaneous devices for occlusion of the LAA (WATCHMAN, WATCHMAN FLX, Amplatzer Amulet) and removed verbiage that the WATCHMAN is the only FDA approved device. Updated background to include information on WATCHMAN FLX and Amplatzer Amulet devices with updated notation that both devices are FDA approved and removed verbiage that the WATCHMAN is the only FDA approved device. Updated AHA/ACC/HRS recommendation in background. References reviewed and updated. Changed "Date" in the revision log header to "Revision Date." Specialist reviewed.	7/22	

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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. LHCC 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.

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