Cohere Medical Policy - Left Atrial Appendage Implants

Clinical Guidelines for Medical Necessity Review

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Important Notices

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Guideline Information:

Specialty Area: Cardiovascular Disease
Guideline Name: Cohere Medical Policy - Left Atrial Appendage Implants

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Type: [**X**] Adult (18+ yo) | [**X**] Pediatric (0-17 yo)

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Recommended Clinical Approach

Left atrial appendage (LAA) implants (WATCHMAN Left Atrial Appendage device and AMPLATZER Amulet Occluder) are alternatives to chronic anticoagulant therapy for patients with nonvalvular atrial fibrillation (in the absence of moderate to severe mitral stenosis or a mechanical heart valve) at increased risk for a stroke. This procedure is a percutaneous catheter-based intervention that serves as an alternative to anticoagulation for patients who have become intolerant to anticoagulation, have poor drug adherence, have an increased risk of bleeding, or have had major bleeding events from recommended anticoagulant regimens.[1-2] This procedure may also be considered for patients with high-risk occupations that place individuals at-risk for bleeding or comorbid conditions requiring treatment that are not compatible with oral anticoagulants. In patients with either (1) A CHA_2DS_2-VASc score of 3 or greater, (2) A hospitalization related to a bleeding event, or (3) A cardioembolic event while on oral anticoagulants, left atrial appendage closure devices were shown to be non-inferior to direct-acting oral anticoagulants (DOACs) at preventing of stroke, systemic embolism, significant bleeding events, and cardiovascular death.[3] There is a risk of procedural complications with these implants, including peri-device leakage, perforation, pericardial tamponade, thrombosis, stroke, and death.[4-6] Oral anticoagulation remains the preferred therapy for stroke prevention for most patients with atrial fibrillation (AF) and elevated stroke risk.[1] Current consensus guidelines favor a trial of oral anticoagulation therapy before considering primary LAA closure.

Medical Necessity Criteria

Indications

- ➔ **Left atrial appendage implant** with an FDA-approved closure device (Amplatzer Amulet, WATCHMAN FLX, WATCHMAN FLX Pro) is considered appropriate if **ALL** of the following are **TRUE** :[5-6]
  - ◆ The patient has non-valvular atrial fibrillation; **AND**

- The patient has an increased risk of stroke and systemic embolism based on **$CHADS_2$** score greater than or equal to 2 (**C**ongestive heart failure, **H**ypertension, **A**ge greater than 75, **D**iabetes, **S**troke/transient ischemic attack/thromboembolism) or **CHA_2DS_2-VASc** score greater than or equal to 3 (**C**ongestive heart failure, **H**ypertension, **A**ge greater than or equal to 65, **D**iabetes, **S**troke/transient ischemic attack/thromboembolism, **V**ascular disease, **S**ex category); **AND**
- Must be able to take short-term oral anticoagulation or antiplatelet therapy post-implantation; **AND**
- **ANY** of the following:
    - The patient has had one or more significant bleeding events requiring hospital treatment related to oral anticoagulation therapy (warfarin or direct-acting oral anticoagulants [DOACs])[2] related to irreversible causes; **OR**
    - The patient has a history of thromboembolic events, including TIA or stroke, despite being treated with oral anticoagulation therapy[7]; **OR**
    - Increased risk of bleeding, characterized by **ANY** of the following:
        - Severe bleeding due to a nonreversible cause involving the gastrointestinal, pulmonary, or genitourinary systems; **OR**
        - Spontaneous intracranial/intraspinal bleeding due to a nonreversible cause; **OR**
        - Serious bleeding related to recurrent falls when the cause of falls is not determined to be treatable.[8]

Non-Indications

➔ **Left atrial appendage implant** is not considered appropriate if **ANY** of the following is **TRUE**:[5-6]

- The patient has atrial fibrillation and is indicated for long-term oral anticoagulation therapy but has not had any trial of warfarin or DOACs[2]; **OR**
- The patient has other medical indications for chronic oral anticoagulant therapy (valve disease, pulmonary embolism, deep vein thrombosis); **OR**

- Inability to perform transseptal puncture due to the presence of an intracardiac mass or an existing atrial septal or patent foramen ovale repair/closure device; **OR**
- LAA anatomy not amenable to percutaneous device closure; **OR**
- Known sensitivity to device components or material; **OR**
- There is a general contraindication for TEE or percutaneous catheterization procedures (patient oropharynx too small for TEE probe or conditions such as active infection or bleeding disorder); **OR**
- Use of anticoagulation therapy, aspirin or a P2Y12 inhibitor (antiplatelet drug) is contraindicated in the patient.[6]

Site of Service Criteria

Outpatient

Procedure Codes (HCPCS/CPT)

HCPCS Code	Code Description/Definition
33340	Percutaneous transcatheter closure of the left atrial appendage with implant, including fluoroscopy, transseptal puncture, catheter placement(s), left atrial angiography, left atrial appendage angiography, radiological supervision and interpretation

Medical Evidence

January et al. (2019) published a guideline update for the American Heart Association, the American College of Cardiology, and the Heart Rhythm Society for the management of patients with atrial fibrillation. Percutaneous LAA occlusion was recommended for consideration in patients with atrial fibrillation and increased risk of stroke with contraindications to long-term anticoagulation. They state that while the FDA approval indicated that the device was restricted to patients deemed suitable for long-term warfarin, as in the inclusion criteria for the clinical trials; however, the CMS criteria indicate that the device is an alternative for patients able to tolerate short-term but not long-term warfarin.[1]

Makkar et al. (2024) reviewed the post-approval study of the use of the Amulet occluder following failure of LAA occlusion. The two FDA-approved devices for LAA occlusion at the time of this publication were Amulet and WATCHMAN, with the Amulet consisting of a dual occlusive mechanism compared with the WATCHMAN device's single mechanism. The authors state that in complex LAA anatomies, failures may occur, particularly with the single mechanism devices. This post-approval study consisted of 8591 patients who underwent Amulet implantation with 244 of these patients having prior failed LAA occlusion. 88.9% of study participants with prior failed LAA occlusion had success with the Amulet implantation. Greater than 90% of patients experienced less than a 3 mm peridevice leak. There was a low rate of adverse events, and the Amulet device was found to facilitate successful closure in challenging LAA anatomies.[9]

Simon et al. (2024) conducted a retrospective study of 649 patients with a mean age of 61.3 plus or minus 10.5 years. 33.9% of the patients in the study were women, and there was a 7.1% rate of previous stroke (4.8%) or transient ischemic attack (2.3%) in the population regardless of gender. The study focused on the effect of LAA morphology on stroke incidence (cauliflower, chicken wing, swan, and windsock) with the swan morphology (4.8% of patients) indicating higher stroke risk (in addition to decreased LAA flow velocity) and the windsock shape proving to be protective against stroke (32.5% of patients).[10]

The US Food and Drug Administration (FDA) granted Premarket Approval (PMA) to Boston Scientific Corporation (2015) for the WATCHMAN Left Atrial Appendage Closure Device with Delivery System in addition to subsequent generation devices, the WATCHMAN FLX and WATCHMAN FLX Pro. The WATCHMAN FLX is stated to occlude a wider size range of LAAs than the first generation device, as well as allow for short-term postoperative use of a DOAC instead of warfarin, as was required with WATCHMAN.[6]

Brouwer and colleagues (2019) conducted a post-hoc analysis of the randomized PROTECT and PREVAIL trials for atrial fibrillation patients with left atrial appendage closure vs. warfarin. 1114 randomized subjects were found to have a net clinical benefit of 1.42% per year with the LAA closure. Warfarin was found to have favorable net clinical benefit early in follow-up, with trends favoring LAA closure after 1-2 years. The group concluded in favor of the long-term benefit of LAA closure due to the reduction in bleeding events and mortality.[11]

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Clinical Guideline Revision History/Information

Original Date: December 1, 2023		
Review History		
Version 2	August 13, 2024	Updated indications, non-indications, references
Version 3	January 9, 2025	• Annual review. • No changes to procedure codes. • Removed indication p.5 related to bleeding risk from oral anticoagulation • Literature review - Medical Evidence section updated, references added.