Left Atrial Appendage Implants - Single Service

Clinical Guidelines for Medical Necessity Review

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Important Notices

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Guideline Information:

Specialty Area: Cardiology
Guideline Name: Left Atrial Appendage Implants

Literature review current through: 12/1/2023
Document last updated: 12/1/2023
Type: [**X**] Adult (18+ yo) | [**X**] Pediatric (0-17yo)

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Service: Left Atrial Appendage Device Implants

General Guidelines

- **Units, Frequency, & Duration:** Single procedure per clinical criteria.
- **Criteria for Subsequent Requests:** None.
- **Recommended Clinical Approach:** Left atrial appendage devices (WATCHMAN Left Atrial Appendage (LAA) 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 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] 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. The WATCHMAN device has been shown to reduce stroke in the setting of atrial fibrillation at about the same rate as warfarin and is non-inferior to warfarin.[2] 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 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.[4,5,6] Oral anticoagulation remains the preferred therapy for stroke prevention for most patients with AF and elevated stroke risk.[1] Current consensus guidelines favor a trial of oral anticoagulation therapy before considering primary LAA closure.
- **Exclusions:** None.

Medical Necessity Criteria

Indications

- ➔ **Left atrial appendage device 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 an increased risk of stroke and systemic embolism based on CHA2DS2-VASc scoring (greater than or equal to 2 for males; greater than or equal to 3 for females); **AND**
  - ◆ Formal, documented, shared decision-making interaction with independent non-interventional physician using an evidence-based decision tool such as the HAS-BLED score has been used to determine suitability for anticoagulation therapy; **AND**
  - ◆ **ANY** of the following:
    - The patient has atrial fibrillation not associated with valve disease and has had one or more significant bleeding events requiring hospital treatment related to oral anticoagulation therapy (warfarin or direct-acting oral anticoagulants [DOACs]); **OR**
    - The patient has had atrial fibrillation and has had thromboembolic events, including TIA or stroke, despite being treated with oral anticoagulation therapy; **OR**
    - The patient has atrial fibrillation with medical conditions that present a significant bleeding risk that precludes oral anticoagulant treatment, including inherited bleeding disorders, severe hepatic or renal dysfunction, and insufficiently treated GI disease with bleeding vascular malformations
    - High-risk occupations or lifestyles that place individuals at-risk for bleeding
    - Increased risk of bleeding

Non-Indications

- ➔ **Left atrial appendage device implant** is **NOT** considered appropriate if **ANY** of the following is **TRUE**:[5,6]
  - ◆ The patient has a CHA_2DS_2-VASc score of less than 3 for females or less than 2 for males or $CHADS_2$ score of less than 2; **OR**
  - ◆ The patient has atrial fibrillation and is indicated for long-term oral anticoagulation therapy but has not had any trial of warfarin or DOACs; **OR**

- The patient has other medical indications for chronic oral anticoagulant therapy (valve disease, pulmonary embolus, deep vein thrombosis); **OR**
- Inability to perform transseptal puncture due to presence of intracardiac mass or atrial septal or patent foramen ovale repair/closure device; **OR**
- LAA anatomy not amenable to 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 P2Y12 inhibitors 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

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 as well as 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]

The Centers for Medicare and Medicaid Services (CMS) published a 2016 National Coverage Decision (NCD) (20.34) for Percutaneous Left Atrial Appendage Closure (LAAC). LAAC is covered by the NCD for non-valvular atrial fibrillation (NVAF) through Coverage with Evidence Development. The device must have received FDA Premarket approval and specific conditions are met, including either CHADS2 or CHA2DS2-VASc scoring as well as surgeon and facility standards criteria.[7]

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]

References

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Clinical Guideline Revision History/Information

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Review History	