Cohere Medical Policy - Left Atrial Appendage Implants

Clinical Guidelines for Medical Necessity Review

Version: 2
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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

Literature review current through: 8/6/2024
Document last updated: 8/13/2024
Type: [**X**] Adult (18+ yo) | [**X**] Pediatric (0-17 yo)

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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 **$CHADS_2$** 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 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; **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.[7]

Non-Indications

- ➔ **Left atrial appendage device 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; **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 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.[8]

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

1. January CT, Wann LS, Calkins H, et al. 2019 AHA/ACC/HRS focused update of the 2014 AHA/ACC/HRS guideline for the management of patients with atrial fibrillation: a report of the American College of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines and the Heart Rhythm Society. *Heart Rhythm*. 2019 Aug;16(8):e66-e93.
2. Brouwer TF, Whang W, Kuroki K, Halperin JL, Reddy VY. Net clinical benefit of left atrial appendage closure versus warfarin in patients with atrial fibrillation: a pooled analysis of the randomized PROTECT-AF and PREVAIL studies. *J Am Heart Assoc*. 2019;8(23):e013525. doi: 10.1161/JAHA.119.013525.
3. Osmancik P, Herman D, Neuzil P, et al. Left atrial appendage closure versus direct oral anticoagulants in high-risk patients with atrial fibrillation. *J Am Coll Cardiol.* 2020;75: 3122-3135.
4. De Backer O, Arnous S, Ihlemann N, et al. Percutaneous left atrial appendage occlusion for stroke prevention in atrial fibrillation: an update *Open Heart* 2014;1:e000020. doi: 10.1136/openhrt-2013-000020.
5. Masoudi FA, Calkins H, Kavinsky CJ, et al. 2015 ACC/HRS/SCAI Left Atrial Appendage Occlusion Device Societal Overview. *J Am Coll Cardiol.* 2015;66(13):1497-1513. doi:10.1016/j.jacc.2015.06.028.
6. US Food and Drug Administration. Summary of Safety and Effectiveness Data. WATCHMAN left atrial appendage closure device with delivery system. https://www.accessdata.fda.gov/cdrh_docs/ pdf13/ P130013S035B.pdf.
7. Joglar JA, Chung MK, Armbruster AL, Benjamin EJ, Chyou JY, et al. 2023 ACC/AHA/ACCP/HRS guideline for the diagnosis and management of atrial fibrillation: a report of the American College of Cardiology/ American Heart Association Joint Committee on Clinical Practice Guidelines. *J Am Coll Cardiol*. 2024;83:109–279.
8. Centers for Medicare and Medicaid Services(CMS). National Coverage Determination (NCD). Percutaneous left atrial appendage closure (LAAC). Effective Date February 8, 2016. https://www.cms.gov/medicare-coverage- database/view/ncd.aspx?n.

Clinical Guideline Revision History/Information

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Review History		
Version 2	August 1, 2024	Updated indications, non-indications, references