Cohere Medicare Advantage Policy - Left Atrial Appendage Implants

Clinical Guidelines for Medical Necessity Review

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Important Notices

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Other Notices:

Guideline Information:

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

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Medical Necessity Criteria

Service: **Left Atrial Appendage Implants**

Benefit Category

Inpatient Hospital Services
Physicians' Services

Please Note: This may not be an exhaustive list of all applicable Medicare benefit categories for this item or service.

Related CMS Documents

Please refer to the CMS Medicare Coverage Database for the most current applicable CMS National Coverage.[1]

- National Coverage Determination (NCD) - Percutaneous Left Atrial Appendage Closure (LAAC) 20.34

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 treatments 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 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.

Evaluation of Clinical Harms and Benefits

Cohere Health uses the criteria below to ensure consistency in reviewing the conditions to be met for coverage of Left Atrial Appendage Implants. This process helps to prevent both incorrect denials and inappropriate approvals of medically necessary services. Specifically, limiting incorrect approvals reduces the risks associated with unnecessary procedures, such as complications from surgery, infections, and prolonged recovery times.

The potential clinical harms of using these criteria may include:

- Blood clot, infection, pericardial effusion, and stroke are potential complications of a left atrial appendage implant. In an incorrectly-selected patient population, these risks may outweigh the potential benefit of the device. This underscores the importance of careful, proper patient selection.[1-3]
- Risks are associated with the transcatheter placement of the device, including pain at the catheterization site, dizziness, and swelling of the incision. The risks of anesthesia and sedation include nausea and vomiting, dizziness, and increased fall risk.[1-3]
- Increased healthcare costs and complications from the inappropriate use of emergency services and additional treatments.

The potential clinical benefits of using these criteria include:

- LAA implants do not require the same lifestyle restrictions as certain anticoagulation medications, such as frequent blood tests, avoidance of certain foods, and abstinence from high-risk sports and activities.[1-3]
- LAA implants do not require open-heart surgery and instead are placed via catheter in the groin or arm, thereby avoiding the lengthy hospital stay, increased cost, and associated nosocomial risks of a traditional open left atrial appendage ligation.[1-3]
- LAA implants have an excellent long-term safety profile and rate of efficacy, serving as a near-lifelong solution for stroke risk mitigation for properly selected patients.[1-3]
- Enhanced overall patient satisfaction and healthcare experience.

This policy includes provisions for expedited reviews and flexibility in urgent cases to mitigate risks of delayed access. Evidence-based criteria are employed to prevent inappropriate denials, ensuring that patients receive medically necessary care. The criteria aim to balance the need for effective treatment with the minimization of potential harms, providing numerous clinical benefits in helping avoid unnecessary complications from inappropriate care.

In addition, the use of these criteria is likely to decrease inappropriate denials by creating a consistent set of review criteria, thereby supporting optimal patient outcomes and efficient healthcare utilization.

Medical Necessity Criteria

Indications

- ➔ A **left atrial appendage implant** is considered appropriate if **ALL** of the following are **TRUE**[1-3]:
  - ◆ The patient has non-valvular atrial fibrillation (NVAF); **AND**
  - ◆ The left atrial appendage occlusion device has received Food and Drug Administration (FDA) Premarket Approval (PMA) for that device's FDA-approved indication, including **ALL** of the following:
    - The patient is recommended for long-term anticoagulation therapy; **AND**
    - The patient is deemed by their physician to be suitable for (short-term) warfarin or DOAC; **AND**
    - The patient has an appropriate, documented rationale (including HASBLED score) to seek a non-pharmacologic alternative to warfarin or DOA; **AND**
    - **ANY** of the following:
      - CHADS2 score of at least 2 (Congestive heart failure, Hypertension, Age of 75 or more, Diabetes, Stroke/transient ischemia attack/thromboembolism); **OR**
      - CHA2DS2-VASc score of at least 3 (Congestive heart failure, Hypertension, Age of 65 or more, Diabetes, Stroke/transient ischemia attack/thromboembolism, Vascular disease, Sex category); **AND**

- The patient is part of a Coverage with Evidence Development (CED) study, registry, or randomized-controlled trial (RCT) investigating left atrial appendage implants that is approved by the Centers for Medicare and Medicaid Services (CMS).

Non-Indications

➔ A **left atrial appendage implant** is not considered appropriate if **ANY** of the following is **TRUE**[1-3]:

- LAAC is non-covered for the treatment of NVAF when not furnished under CED according to the above-noted criteria; **OR**
- The subject requires long-term anticoagulation therapy for reasons other than AF-related stroke risk reduction; **OR**
- The subject has a contraindication for short-term anticoagulant therapy with DOAC post-implantation; **OR**
- The patient is contraindicated to aspirin and/or clopidogrel; **OR**
- Intracardiac thrombus is present; **OR**
- The LAA anatomy will not accommodate a closure device; **OR**
- The patient has a known hypersensitivity to any portion of the device material or the individual components; **OR**
- The patient has a history of atrial septal repair or has an atrial septal defect (ASD) or patent foramen ovale (PFO) closure device; **OR**
- The patient has an implanted mechanical valve prosthesis in any position; **OR**
- The patient has New York Heart Association class IV heart failure or Stage D heart failure on a mechanical assist or heart replacement device; **OR**
- Physical limitations that preclude device implantation, including small patient size such that necessary TEE probe or catheters are unable to placed; **OR**
- Active infection; **OR**
- Leg ulcers are present; **OR**
- Bleeding disorder (e.g., hemophilia, Von Willebrand, etc.).

Level of Care Criteria

Outpatient

Procedure Codes (CPT/HCPCS)

CPT/HCPCS Code	Code Description

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

Disclaimer: G, S, I, and N Codes are non-covered per CMS guidelines due to their experimental or investigational nature.

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 in addition to subsequent generation devices, the WATCHMAN FLX and WATCHMAN FLX Pro (2020). The WATCHMAN FLX is stated to occlude a wider size range of LAAs than the first-generation device, as well as to allow for short-term postoperative use of a DOAC instead of warfarin, as was required with WATCHMAN. A similar device, known as the Amplatzer Amulet Left Atrial Appendage Occluder, received PMA in 2021.[1-3]

Makkar et al. (2024) reviewed the post-approval study 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 versus the WATCHMAN device's single mechanism. The authors state that in complex LAA anatomies, failures may occur, particularly with single-mechanism devices. This post-approval study consisted of 8591 patients who underwent Amulet implantation, of which 244 patients failed prior LAA occlusion. 88.9% of study participants with prior failed LAA occlusion had success with the Amulet implantation. There was a low rate of adverse events, and the Amulet device was found to facilitate successful closure in challenging LAA anatomies.[9]

The Journal of Cardiology published an overview of current indications for left atrial appendage closure in 2025. The authors note the utility of nonpharmacologic stroke risk mitigation among certain groups, including patients with end-stage renal disease on hemodialysis and patients with hereditary bleeding disorders (e.g., hemophilia). Importantly, they highlight that, amid the acceptable safety profile and efficacy of LAAC devices, the most concerning complication is device-associated thrombi - although a number of potentially modifiable predictive risk factors are identified (e.g., large volume of remaining uncovered appendage, inappropriate device size selection, deep device implantation). The authors also emphasize the optimal selection of patients who are able to tolerate the required short-term oral anticoagulants following implantation.[15]

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Clinical Guideline Revision History/Information

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