



Clinical Review Criteria

Left Atrial Appendage (LAA) Closure Therapy

- Watchman, Amplatzer Amulet (percutaneous)
- AtriClip (non-percutaneous, used during surgical procedures)

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Criteria

**Please send all cases to Medical Director for review.*

For Medicare Members

| Source | Policy |
|--|---|
| CMS Coverage Manuals | None |
| National Coverage Determinations (NCD) | Percutaneous Left Atrial Appendage Closure (LAAC) (20.34) |
| Local Coverage Determinations (LCD) | None |
| Local Coverage Article | Decision Memo for Percutaneous Left Atrial Appendage (LAA) Closure Therapy (CAG-00445N) |
| KPWA Policy | Due to the absence of an active NCD, LCD, or other coverage guidance for <u>non-percutaneous</u> left atrial appendage closure devices, Kaiser Permanente has chosen to use their own Clinical Review Criteria, Left Atrial Appendage (LAA) Closure Therapy , for medical necessity determinations. Refer to the Non-Medicare criteria II.B. below regarding non-percutaneous closure. |

For Non-Medicare Members

- I. Percutaneous LAA appendage closure using a device approved by the FDA (e.g., the Watchman or Amplatzer Amulet) is approved for patients with atrial fibrillation who meet **ALL of the following criteria**:
 - A CHA2DS2-VASc score ≥ 3
 - Patient is suitable for short-term warfarin but deemed unable to take long term oral anticoagulation (neither Warfarin nor DOACs) following the conclusion of shared decision making, as LAAC is only covered as a second line therapy to oral anticoagulants.
 - The patient is formally evaluated by a multidisciplinary Heart Team of medical professionals who document a collaborative recommendation for LAA occlusion.
 - The procedure must be furnished in a hospital with established cardiac surgery, structural heart disease, and electrophysiology (EP) programs.
 - A formal shared decision-making interaction with an independent non-interventional cardiologist (not part of procedural treatment team) using an evidence-based decision tool on oral anticoagulation in patients with NVAf prior to LAAC. Additionally, the shared decision-making interaction must be documented in the medical record.
 - The procedure must be performed by an interventional cardiologist(s), electrophysiologist(s) or cardiovascular surgeon(s) that meets accepted CMS criteria for training/implantation ([see Medicare NCD](#))
 - The patient is enrolled in, and the MDT and hospital must participate in a prospective, national, audited registry.

II. The use of any other left atrial appendage devices are considered investigational, including but not limited to any of the following:

- Devices not approved by the FDA for percutaneous LAA closure (e.g., LARIAT or PLAATO devices).
- Devices used during surgical procedures (**non-percutaneous**) to occlude the LAA (e.g., AtriClip is not medically necessary).

If requesting these services, please send the following documentation to support medical necessity:

- Last 6 months of clinical notes from requesting provider &/or specialist
- Last 6 months of radiology notes if applicable

The following information was used in the development of this document and is provided as background only. It is provided for historical purposes and does not necessarily reflect the most current published literature. When significant new articles are published that impact treatment option, Kaiser Permanente will review as needed. This information is not to be used as coverage criteria. Please only refer to the criteria listed above for coverage determinations.

Background

Atrial fibrillation (AF) is the most common sustained cardiac arrhythmia, affecting more than 5.5 million individuals in the US, and its prevalence is increasing with the aging population. AF leads to loss of organized atrial contractions, which results in blood stasis in the atrium and thrombus formation with the potential for embolization leading to stroke. It is reported that the risk of ischemic stroke is up to 5 times higher in patients with AF. This risk of cardioembolic stroke varies from one individual to the other based on other risk factors and comorbidities, but overall it increases considerably with age from 1.5% in patients 50-59 years of age to 23.5% for those 80-89 years of age. Stroke prophylaxis is thus an important component in managing patients with non-valvular AF (Holmes 2009, Reddy 2013, Bode 2015).

Antiarrhythmic drugs, and catheter ablation of AF may provide relief of symptoms, but do not sufficiently prevent the occurrence of thromboembolic events. Long-term oral anticoagulant therapy is the standard of care for effective stroke prevention in AF patients at high risk for thromboembolism according to clinical risk scores such as the CHADS2 and the CHA2DS2-VASc models. Warfarin is highly effective in reducing stroke in at-risk patients with AF, but is often not well tolerated by all patients, has a very narrow therapeutic range, and is associated with a high risk of bleeding. In addition, its effectiveness may vary due to its interactions with some foods and medications resulting in the need for frequent monitoring and dose adjustments. It is reported that 50% of the patients' blood test results are outside the therapeutic range. These limitations as well as intolerance or contraindications to warfarin in some patients have led to the non-use or discontinuation of the drug in a large proportion of AF patients, particularly the older patients who are at an increased risk of stroke. The more recently developed oral anticoagulant agents (NOACs) have overcome many of warfarin's limitations, but also need lifelong use and carry the potential risk of bleeding at similar or lower rates than warfarin, depending on the agent used (Sick 2007, Holmes 2009, Alli 2013, Reddy 2013, Price 2014).

Researchers have been investigating non-pharmacological alternatives for patients with intolerance or contraindication to anticoagulant therapy. It is believed (based on echocardiography and autopsy studies) that more than 90% of the atrial thrombi in patients with non-valvular AF, originate in the left atrial appendage (LAA), which is an embryonic remnant of the original embryonic left atrium. LAA is a long tubular trabeculated structure continuous with the atrial cavity. The location and the discrete nature of the LAA have led to the development of a number of techniques for excluding it from the systemic circulation. These include its surgical excision or obliteration by surgical ligation, or by the use of implantable devices via mini thoracotomy or percutaneously. These devices include the St Jude Amplatzer® cardiac plug, Coherex WaveCrest® LAA occlusion system, LARIAT® device, the PLAATO system, and the WATCHMANTM LAA system. The latter is the focus of the current review (McCabe 2009, Holmes 2009, Alli 2014).

The WATCHMANTM (WM) left atrial appendage closure (LAAC) system (Boston Scientific Corp., Maple Grove, Minnesota) is the most intensely studied for LAA occlusion. It is a 3-part system consisting of a trans-septal access sheath, a delivery catheter, and an implantable nitinol (nickel titanium) device. The system is designed to facilitate the device placement through femoral venous access via transseptal route into the LAA. The implantable device is parachute-shaped and comprises a self-expanding nitinol frame structure with fixation barbs to secure it in the LAA, and a permeable polyester membrane that covers the atrial facing surface of the device. The WM

implant is available in 5 sizes (21, 24, 27, 30, and 33 mm) and is typically chosen 10-20% larger than the LAA body to have sufficient compression for stable positioning to minimize the risk of device embolization. The procedure is performed in the cardiac catheterization laboratory under general anesthesia. Transseptal access is obtained using standard techniques guided by fluoroscopic or transesophageal echocardiography (TEE). Once access is gained into the left atrium (LA), a variety of approaches can be used to place the guidance sheath. A pigtail angiographic catheter is then inserted into the sheath which is advanced into the distal portion of the LAA. Once this catheter is placed, the sheath is advanced over it into the LAA. Positioning of the sheath is of critical importance as the LAA is thin-walled and fragile and may be damaged or perforated. Anticoagulation is necessary and it is also important to avoid the potential for air embolism during the procedure. WM is permeable to blood and thus the patients require post-procedure warfarin therapy for 45 days with INR between 2.0 and 3.0 for those who are eligible for warfarin or other equivalent. A TEE is performed for device assessment at 45 days after which a decision is made to discontinue warfarin. After warfarin is discontinued, the patient is treated with clopidogrel 75 mg and aspirin 81-325 mg for 6 months following the implantation, after which the clopidogrel is discontinued and aspirin is used indefinitely (Sick 2007, Alli 2014, Holmes 2015).

As with other invasive procedures, the techniques and devices used for LAA closure including WATCHMANTM have potential complications including pericardial effusion, procedure-related stroke, device thrombosis, device embolization, bleeding, arrhythmia, access site complications, arteriovenous fistula, and pseudoaneurysm formation (Alli 2014). More recently on April 23, 2015, the FDA recalled the TigerPaw II (Maquet, Rastatt, Germany) LAA closure device following reports that the device could cause tearing of the left atrial wall and bleeding.

The WATCHMANTM device received FDA approval in 2015 as an alternative to commonly-used blood thinners to prevent stroke in patients with atrial fibrillation who are at an increased risk of stroke and systemic embolism based on CHADS2 or CHA2DS2-VASc and are recommended for anticoagulation therapy; are deemed by their physicians to be suitable for warfarin; and have an appropriate rationale to seek a non-pharmacologic alternative to warfarin, taking into account the safety and effectiveness of the device compared to warfarin. The FDA had initially declined the approval of the device twice before the final approval due of concerns about its safety and effectiveness, including the complications while implanting the device.

Medical Technology Assessment Committee(MTAC)

Watchman

08/17/2015: MTAC REVIEW

Evidence Conclusion: The published evidence does not support the use of Watchman LAA occlusion device for the prevention of stroke in in patients with nonvalvular atrial fibrillation. Ideally a new therapy or intervention would be at least equivalent or noninferior (if not superior), to the gold standard treatment with regard to safety, efficacy, and long term outcomes. To date, LAAC closure with Watchman system in patients with nonvalvular atrial fibrillation has not fulfilled the safety requirement in the two pivotal trials, nor the efficacy requirement in the PREVAIL trial. The PROTECT AF trial showed that occluding the LAA with the Watchman device is feasible and with noninferior efficacy than warfarin in reducing the composite risk of stroke, cardiac death, or systemic embolism as primary prevention therapy in patients with CHADS2 >1. In the PREVAIL trial that included higher risk patients, the device did not reach the noninferiority level for the primary efficacy composite endpoint of ischemic or hemorrhagic stroke, cardiovascular or unexplained death, or systemic embolism. More recent long-term follow-up data from PROTECT AF show that the device remained noninferior to warfarin use as regards its efficacy but not its safety. More recent long-term follow-up data from PREVAIL trial show that the 2 first primary endpoints of the trial do not meet the prespecified noninferiority end point of the study. There is evidence from the published RCTs that the occlusion of the LAA with the Watchman device is associated with high risk of procedure-related ischemic stroke and device embolism, as well as other adverse events including serious pericardial effusion and major bleeding. There is insufficient evidence from well-designed RCTs to determine the efficacy and safety of Watchman in patients with a contraindication or intolerance to warfarin or other blood thinners. There is insufficient published evidence from well-designed RCTs to determine the efficacy and safety of Watchman device to other LAA occluding devices or surgical interventions in patients with nonvalvular atrial fibrillation. There is no published study to date, that compared the efficacy and safety of LAA occlusion to any of the NOACs, that demonstrated (from large RCTs) to be either noninferior or superior to warfarin in reducing stroke or systemic embolism with similar or lower rates of major hemorrhage. There are currently 11 ongoing trials on LAA occlusion/excision that may add more information on the safest and most effective intervention for the prevention of stroke in patients with non-valvular atrial fibrillation. WATCHMAN LAA closure device was reviewed by the Kaiser Interregional New Technologies Committee (INTC) in June 1st, 2015. The Committee used the Blue Cross Blue Shield TEC Assessment Program as their primary evidence source and updated the review with new

evidence that would change the TEC results or conclusions. Both TEC and INTC concluded that the evidence was insufficient to determine that WATCHMAN LAAC is medically appropriate for stroke prevention for patients with nonvalvular atrial fibrillation.

Articles: The literature search identified two randomized controlled trials (PROTECT AF and PREVAIL), a nonrandomized prospective study, and a pilot observational study on Watchman LAA occlusion system. All studies were conducted mainly by the same group of principal investigators. The literature search also identified a more recent meta-analysis of the two RCTs also conducted by the same investigators, and another meta-analysis of observational studies (with no control groups) that examined different devices used in the percutaneous occlusion of the left atrial appendage. The two RCTs on Watchman LAA closure device and the meta-analysis pooling their results were selected for critical appraisal. Holmes DR, Reddy VY, Turi ZG, et al. Percutaneous closure of the left atrial appendage versus warfarin therapy for prevention of stroke in patients with atrial fibrillation: a randomized non-inferiority trial. *Lancet*. 2009; 374 (9689):534-542. [See Evidence Table 1](#). Holmes DR Jr, Kar S, Price M, et al. Prospective randomized evaluation of the Watchman Left Atrial Appendage Closure device in patients with atrial fibrillation versus long-term warfarin therapy: the PREVAIL trial. *J Am Coll Cardiol*. 2014 Jul 8; 64 (1):1-12. [See Evidence Table 2](#). Holmes DR Jr, Doshi SK, Kar S, et Al. Left Atrial Appendage Closure as an Alternative to Warfarin for Stroke Prevention in Atrial Fibrillation: A Patient-Level Meta-Analysis. *J Am Coll Cardiol*. 2015 Jun 23; 65(24):2614-23. [See Evidence Table 3](#). Bode WD, Patel N, Gehi AK. Left atrial appendage occlusion for prevention of stroke in nonvalvular atrial fibrillation: a meta-analysis. *J Interv Card Electrophysiol*. 2015 June; 43:79-89.

The use of the Watchman does not meet the *Kaiser Permanente Medical Technology Assessment Criteria*.

Applicable Codes

Considered Medically Necessary when criteria in the applicable policy statements listed above are met:

| CPT® or HCPC Codes | Description |
|--------------------|--|
| 33340 | Percutaneous transcatheter closure of the left atrial appendage with endocardial implant, including fluoroscopy, transeptal puncture, catheter placement(s), left atrial angiography, left atrial appendage angiography, when performed, and radiological supervision and interpretation |

Considered not medically necessary:

| CPT® or HCPC Codes | Description |
|--------------------|---|
| 33267 | Exclusion of left atrial appendage, open, any method (eg, excision, isolation via stapling, oversewing, ligation, plication, clip) |
| 33268 | Exclusion of left atrial appendage, open, performed at the time of other sternotomy or thoracotomy procedure(s), any method (eg, excision, isolation via stapling, oversewing, ligation, plication, clip) (List separately in addition to code for primary procedure) |
| 33269 | Exclusion of left atrial appendage, thoracoscopic, any method (eg, excision, isolation via stapling, oversewing, ligation, plication, clip) |

***Note:** Codes may not be all-inclusive. Deleted codes and codes not in effect at the time of service may not be covered.

**To verify authorization requirements for a specific code by plan type, please use the [Pre-authorization Code Check](#).

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| Creation Date | Review Dates | Date Last Revised |
|---------------|---|-------------------|
| 08/17/2015 | 09/01/2015 ^{MPC} , 06/07/2016 ^{MPC} , 04/04/2017 ^{MPC} , 02/06/2018 ^{MPC} , 01/08/2019 ^{MPC} , 01/07/2020 ^{MPC} , 01/05/2021 ^{MPC} , 01/04/2022 ^{MPC} , 01/10/2023 ^{MPC} | 02/01/2022 |

^{MPC} Medical Policy Committee

| Revision History | Description |
|-------------------------|--|
| 02/07/2017 | MPC approved to adopt criteria for commercial members |
| 03/14/2017 | Added AtriClip |
| 04/02/2019 | MPC approved to update criteria to include Warfarin and DOACs |
| 01/18/2022 | Updated applicable coding with new codes effective 1/1/22 (33267, 33268, 33269) for non-percutaneous left atrial appendage exclusion/closure. |
| 02/01/2022 | MPC approved to update criteria to clarify that only FDA approved percutaneous devices such as the Watchman or Amplatz Ampule are covered. Any other LAA devices are considered not medically necessary, and no device inserted during an open procedure are currently covered. Requires 60-day notice, effective date 07/01/2022. |