


MEDICAL POLICY	Cardiac: Left Atrial Appendage Devices (All Lines of Business Except Medicare)	
Effective Date: 06/01/2020  6/1/2020	Section: SUR	Policy No: 170
	Technology Assessment Committee Approved Date: 7/13;7/14; 4/15; 2/16 Medical Policy Committee Approved Date: 12/17; 7/18; 8/19; 05/2020	
Medical Officer	Date	

See Policy CPT/HCPCS CODE section below for any prior authorization requirements

SCOPE:

Providence Health Plan, Providence Health Assurance, Providence Plan Partners, and Aycin Health Solutions as applicable (referred to individually as “Company” and collectively as “Companies”).

APPLIES TO:

All lines of business except Medicare

BENEFIT APPLICATION

Medicaid Members

Oregon: Services requested for Oregon Health Plan (OHP) members follow the OHP Prioritized List and Oregon Administrative Rules (OARs) as the primary resource for coverage determinations. Medical policy criteria below may be applied when there are no criteria available in the OARs and the OHP Prioritized List.

POLICY CRITERIA

- I. The use of the Watchman device for percutaneous left atrial appendage (LAA) closure may be considered **medically necessary and covered** for the prevention of thromboembolism in patients with non-valvular atrial fibrillation (AF) when **all** the following criteria are met (A. - D.):
 - A. There is an moderate to high risk for stroke and systemic embolism based on CHADS₂ or CHA₂DS₂-VASc score of ≥ 1 (see [Policy Guidelines](#) below for more information on CHADS₂ and CHA₂DS₂-VASc scores); **and**
 - B. A non-pharmacologic alternative to long-term (> 45 days) anticoagulation therapy is recommended and documented in the clinical notes; **and**
 - C. A physician has determined the patient is suitable for short-term (≤ 45 days) warfarin therapy; **and**
 - D. **None** of the following contraindications are present (1. – 7.):

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1. Intracardiac thrombus is visualized by echocardiographic imaging.
2. An atrial septal defect repair or closure device or a patent foramen ovale repair or closure device is present.
3. The left atrial appendage anatomy will not accommodate a device.
4. Any of the customary contraindications for other percutaneous catheterization procedures (e.g., patient size too small to accommodate transesophageal echocardiography [TEE] probe or required catheters) or conditions (e.g., active infection, bleeding disorder) are present.
5. Short-term (≤ 45 days) contraindication to anticoagulation therapy (such as warfarin);
6. Contraindication to antiplatelet (such as clopidogrel or aspirin)
Note: contraindications may include but are not limited to allergy, hypersensitivity, or inability to tolerate. (Please see [Policy Guidelines](#) below for more information on pharmacological contraindications)
7. The patient has a known hypersensitivity to any portion of the device material or the individual components.

- II. The use of left atrial appendage devices are considered **investigational and not covered** when criterion I., above is not met, including but not limited to:
- A. Devices not approved by the FDA for percutaneous LAA closure (e.g., LARIAT, PLAATO, AMPLATZER devices).
 - B. Devices used during surgical procedures (non-percutaneous) to occlude the LAA (e.g., AtriClip).
 - C. When any of the contraindications noted in criterion I.D. are present.

Link to [Policy Summary](#)

POLICY GUIDELINES

Risk Stratification Schemes for Ischemic Stroke^{1,2}

1. **CHADS₂** (Congestive heart failure, Hypertension, Age ≥ 75 years, Diabetes mellitus, prior Stroke or TIA or thromboembolism [doubled])
2. **CHA₂DS₂-VASc** (Congestive heart failure, Hypertension, Age ≥ 75 years [doubled], Diabetes mellitus, prior Stroke or TIA or thromboembolism [doubled], Vascular disease, Age 65 to 74 years, Sex category)

2012 Guidelines from the American College of Chest Physicians² recommend the use of oral anticoagulation for patients with atrial fibrillation (AF) who are at risk of stroke based on the following CHADS₂ risk stratification scores:

1. Score of 1 = moderate risk of stroke
2. Score ≥ 2 = High risk of stroke

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2014 Guidelines from the American Heart Association (AHA)/American College of Cardiology (ACC)/Heart Rhythm Society (HRS)¹ recommend the use of oral anticoagulation for patients with AF who are at risk of stroke based on the CHA₂DS₂-VASc risk stratification score of ≥ 2 .

Of note, in both scoring systems, a score of 0 is "low" risk of stroke, 1 is "moderate", and any score above 1 is a "high" risk. The CHA₂DS₂ system, having three more potential variables, inevitably classifies more patients into a high-risk group.³

The following tables have been adapted from the 2014 AHA/ACC/HRS Guideline for the Management of Patients With Atrial Fibrillation:¹

CHADS₂ Risk Stratification Score	
Risk Factor	Score
Congestive Heart Failure	1
Hypertension	1
Age ≥ 75 years	1
Diabetes Mellitus	1
Prior Stroke/Transient ischemic attack/Thromboembolic	2
Maximum score	6

CHA₂DS₂-VASc Risk Stratification Score	
Risk Factor	Score
Congestive Heart Failure	1
Hypertension	1
Age ≥ 75 years	2
Diabetes Mellitus	1
Prior Stroke/Transient ischemic attack/Thromboembolic	2
Vascular disease (prior myocardial infarction, peripheral artery disease, or aortic plaque)	1
Age 65 to 74 years	1
Sex category (i.e., female sex)	1
Maximum score	9

Watchman Post-Procedural Protocol

According to the FDA label and the device manufacturer's (Boston Scientific) directions for use, there is specific post-procedure pharmacological protocol that must be adhered to.^{4,5} (See flow diagram below). This protocol is as follows:

- A. “Post-procedure warfarin therapy is required in ALL patients receiving a WATCHMAN Device. Patients should remain on 81-100 mg of aspirin and warfarin should be taken post-implant (INR 2.0-3.0). At 45 days (± 15 days) post-implant, perform WATCHMAN Device assessment with TEE. Cessation of warfarin is at physician discretion provided that any peri-device flow demonstrated by TEE is ≤ 5 mm. If adequate seal is not demonstrated, subsequent warfarin cessation decisions are contingent on demonstrating flow ≤ 5 mm. At the time the patient ceases warfarin, the

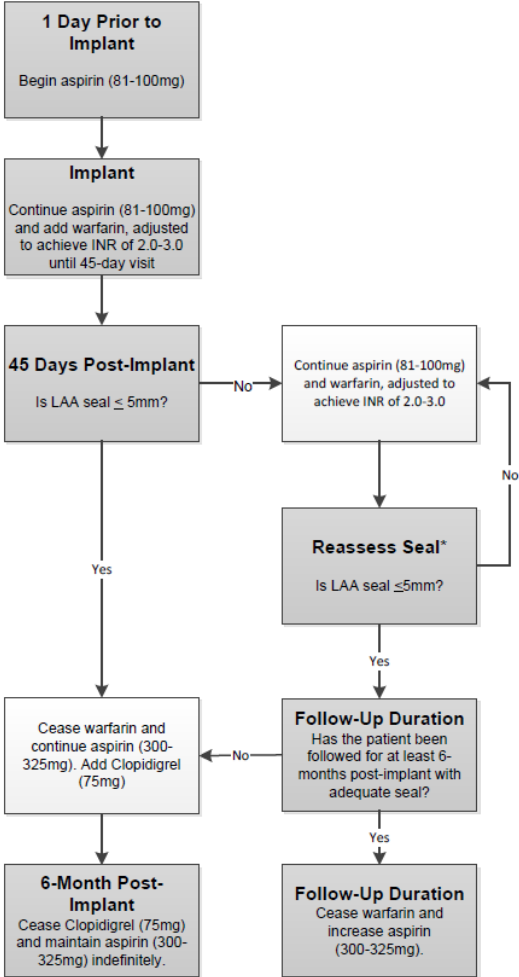
patient should begin clopidogrel 75 mg daily and increase aspirin dosage to 300-325 mg daily. This regimen should continue until 6 months have elapsed after implantation. Patients should then remain on aspirin 300-325 mg indefinitely. If a patient remains on warfarin and aspirin 81-100 mg for at least 6 months after implantation, and then ceases warfarin, the patient should not require clopidogrel, but should increase to aspirin 300-325 mg daily, which should be taken indefinitely.”

- B. At 45 days: assess WATCHMAN Device with TEE.
- Confirm absence of intra-cardiac thrombus.
 - If thrombus is observed on the device, warfarin therapy is recommended until resolution of thrombus is demonstrated by TEE.
 - Perform color Doppler assessment to include the device/LAA border at the following approximate TEE angles (0°, 45°, 90° and 135°). Measure any residual leak around the device if necessary.
 - If the LAA seal is \leq 5mm, cease warfarin and continue aspirin (300-325mg). Add Clopidogrel (75mg). Continue regimen for 6 months post-implant.
 - If the LAA seal is $>$ 5mm on this device, continue warfarin and aspirin (81-100mg) for 6 months post-implant.
- C. 6-months post-implant:
- Patients on clopidogrel and aspirin: cease clopidogrel and continue on with aspirin 300-325 mg indefinitely
 - Patients on warfarin and aspirin: cease warfarin and increase to aspirin 300-325 mg daily, which should be taken indefinitely

As such, patients must have the “ability to comply with the recommended post-WATCHMAN Device implant pharmacologic regimen, especially for patients at high risk for bleeding, i.e., the need for warfarin plus aspirin for at least 45 days post-device implantation, clopidogrel and aspirin through 6 months post-procedure, and aspirin indefinitely.” **Therefore we define a contraindication to short-term warfarin use as the inability to tolerate warfarin for 45 days or less.**

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Per the FDA labeling information and the manufacturer’s directions for use:^{4,5}



Precautions

Per the FDA labeling information and the manufacturer’s directions for use:^{4,5}

“In view of the concerns that were raised by the RE-ALIGN2 study of dabigatran in the presence of prosthetic mechanical heart valves, caution should be used when prescribing oral anticoagulants other than warfarin in patients treated with the WATCHMAN Device. The WATCHMAN Device has only been evaluated with the use of warfarin post-device implantation.”

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Patient Selection for Treatment

Per the FDA labeling information and the manufacturer’s directions for use:^{4,5}

“In considering the use of the WATCHMAN Device, the rationale for seeking an alternative to long-term warfarin therapy and the safety and effectiveness of the device compared to warfarin should be taken into account.”

BILLING GUIDELINES

C1760 is the only supply code that is appropriate for billing with CPT code 33340.

CPT/HCPCS CODES

All Lines of Business Except Medicare	
Prior Authorization Required	
33340	Percutaneous transcatheter closure of the left atrial appendage with endocardial implant, including fluoroscopy, transseptal puncture, catheter placement(s), left atrial angiography, left atrial appendage angiography, when performed, and radiological supervision and interpretation
No Prior Authorization Required	
C1760	Closure device, vascular (implantable/insertable)
The code below is not covered when billed with 33340	
No Prior Authorization Required	
C2628	Catheter, occlusion

DESCRIPTION

Atrial Fibrillation and Stroke

Background

Atrial fibrillation (AF) is a supraventricular, accelerated heart rhythm (tachyarrhythmia) characterized by uncoordinated atrial activation that leads to inefficient, irregular atrial contraction.¹ These irregular contractions can lead to the formation of thrombi. Stroke occurs when thrombi formed in the atria or, more commonly, in the left atrial appendage, enter the systemic circulation and travel to the brain, cutting off circulation to an area of the brain.⁶

The presence of AF increases the risk of death in men and women and reduces the usual survival advantage of women. AF is an independent risk factor for stroke occurrence, severity, recurrence and

mortality. AF accounts for 1.5% of strokes among people 50 to 59 years of age and 23.5% among individuals 80 to 89 years of age.⁷

Treatment

Treatment goals for AF include managing arrhythmia and preventing thromboembolism and stroke. Arrhythmia management is achieved through electrical or pharmacologic cardioversion. The standard care for stroke prevention in patients with AF is anticoagulation with vitamin K antagonists (e.g., warfarin) or newer oral anticoagulants (OACs) (i.e., apixaban, dabigatran, edoxaban, rivaroxaban).⁶ However, OAC is associated with a risk of bleeding and some patients have relative or absolute contraindications to OAC, while others are unable to adhere to long-term treatment with OAC. These limitations of OAC therapy have spurred the development of non-pharmaceutical approaches to prevent stroke in patients with AF by occluding the left atrial appendage (LAA).⁷

Left Atrial Appendage (LAA)

The LAA is a 2-4 centimeter tubular structure connected to the left atrium through a narrow junction. It has been reported that atrial thrombi are located within the LAA in 89% of patients with non-valvular atrial fibrillation (NVAf), in 78% of non-anticoagulated patients with NVAf, and in 44% of patients with valvular AF.⁷ LAA occlusion may be achieved by either surgical excision or occlusion, or via percutaneously inserted devices.

Surgical excision of the LAA is not within the scope of this policy and is therefore not reviewed further.

Percutaneous Devices

Watchman (Boston Scientific Corp.)

The Watchman LAA closure device is a self-expandable, open-ended nitinol basket that is permeable to blood. The device is permanently anchored into the ostium of the LAA to trap blood clots before they exit the LAA in patients with non-valvular atrial fibrillation. The three-part system consists of a transeptal access sheath, a delivery catheter, and a self-expanding nitinol frame with fixation barbs covered with a permeable polyester fabric and preloaded into a proprietary delivery catheter, which is designed to allow device recapture if necessary.⁷ Currently, this device is the only percutaneous device approved by the United States Food & Drug Administration (FDA) LAA closure/occlusion.⁴ It is intended for use in patients for whom anticoagulation therapy is recommended but seek a non-pharmacologic alternative to long-term anticoagulation therapy.

AMPLATZER™ Cardiac Plug (ACP) (St. Jude Medical / Abbott)

The AMPLATZER™ Cardiac Plug (ACP) is a transcatheter, self-expanding device that is anchored into the neck of the LAA.⁷ The device requires an LAA depth of 10 mm and includes a left atrial disc designed to completely seal the LAA orifice. The ACP consists of nitinol and interwoven polyester materials in an effort to promote occlusion and tissue in-growth. The technique for implanting this device is also similar

to that of the Watchman system. However, although this device is approved for LAAC in Europe, it is not approved by the FDA for LAAC in the United States.

AMPLATZER™ Amulet™ (St. Jude Medical / Abbott)

The AMPLATZER™ S Amulet™ is a self-expanding, second-generation device made of the same components and inserted in the same location in the LAA as its predecessor, the AMPLATZER™ ACP.⁷ The device has additional features intended to reduce the occurrence of embolization and incomplete LAA exclusion that has been reported with the ACP, including availability in a broader size range (11 to 31 mm in diameter).⁸ This device is still undergoing clinical trials and has not been approved by the FDA for any indication.

LARIAT® Suture Delivery Device (SentreHEART Inc.)

The LARIAT® Suture delivery device is a remote suture delivery system that utilizes a 40mm pre-tied suture loop and collapsible snare to close soft tissues without the use of metal, clip or implant. According to the FDA, its intended use is to facilitate suture placement and knot tying in surgical applications where soft tissues are being ligated with a polyester suture.⁹ The technical approach differs from that of the Watchman system in that the suture loop ligates the LAA from the epicardial space, with assistance of catheters and balloons in the left atrium.⁷ Although the Lariat® device has been FDA approved as a suture delivery device, it does not have approval as an LAAC device.⁹ Therefore, the use of this suture system for LAA closure is considered off-label use.

Non-Percutaneous Devices

AtriClip® (AtriCure, Inc.)

AtriClip LAA Exclusion Systems include a clip device that is placed at the base of the LAA to permanently occlude it from the circulating blood in the left atrium.¹⁰

The AtriClip LAA exclusion systems have been approved by the FDA for the occlusion of the LAA, under direct visualization and in conjunction with other open cardiac surgical procedures. The FDA 510(k) premarket notification states that direct visualization, in this context, requires “that the surgeon is able to see the heart directly, without assistance from a camera, endoscope, etc., or any other viewing technology. This includes procedures performed by sternotomy (full or partial) as well as thoracotomy (single or multiple).”¹¹

REVIEW OF EVIDENCE

Percutaneous Left Atrial Appendage Closure/Occlusion Devices

The medical necessity criteria for the Watchman device are primarily based on clinical rationale for use in patients seeking a non-pharmacologic alternative to long-term anticoagulation therapy. Given this, and that the Watchman is the only FDA-approved percutaneous LAA closure/occlusion device, an evidence review for the Watchman device was not conducted at this time. Neither the LARIAT® Suture

delivery device nor the AMPLATZER™ devices (Cardiac Plug or Amulet™) have been approved by the FDA for LAA closure or occlusion. The health plan considers devices that are not FDA-approved to be investigational and not covered.

Left Atrial Appendage Closure/Occlusion using Surgical Techniques

The only device that is currently FDA-approved and on the market for LAA occlusion during surgery is the AtriClip. However, the AtriClip is only currently approved for use during heart surgery under direct visualization (including open and thoracoscopic procedures). Therefore, a review of the ECRI, Hayes, Cochrane, and PubMed databases was conducted regarding the use of AtriClip for its approved indications. Below is a summary of the available evidence identified through April of 2020.

In 2017, Caliskan et al. published the largest study evaluating the safety and efficacy of the AtriClip device, including 291 patients (40 prospectively recruited to undergo open-heart surgery and 251 retrospectively reviewed from a registry of patients who had previously received the AtriClip.).¹² Overall mean follow-up was 36± 23months (range: 1–97months). The authors reported high rates of successful occlusion, low rates of adverse events and promising long-term data. However, the study had several limitations, including poor study design (single-center, no comparator group and retrospective analyses performed), lack of systematic and rigorous follow-up, wide range of follow-up, and concomitant surgical ablations performed in some patients which likely impacted outcomes. In addition, long-term data (5-year analyses) were only reported on 32 patients. The authors concluded that data from large randomized controlled trials are needed to evaluate the AtriClip device in regard to stroke-prevention compared with current pharmacological and interventional therapies.

Additional evidence evaluating the safety and efficacy of the AtriClip device during open-heart surgery consists of small to medium sized case series (n=30-71)¹³⁻¹⁶ and small retrospective chart reviews (n=20-24 patients).^{17,18} All of these studies suffer from the same limitations, including poor study design (single-center, no comparator group), short-term follow-up (3 – 18 months) and inclusion of patients receiving concurrent ablation for atrial fibrillation. Overall, large multicenter RCTs are needed to evaluate the safety and long-term efficacy of the AtriClip device in the prevention of stroke.

CLINICAL PRACTICE GUIDELINES

American Heart Association/American Stroke Association (AHA/ASA)

The 2014 AHA/ASA joint guidelines regarding primary prevention of stroke recommended the following.¹⁹

“Closure of the left atrial appendage may be considered for high-risk patients with atrial fibrillation who are deemed unsuitable for anticoagulation if performed at a center with low rates of periprocedural complications and the patient can tolerate the risk of at least 45 d of postprocedural anticoagulation (Class IIb; Level of Evidence B).”

Although the guideline did not call out the Watchman device specifically, the studies used as a basis for this recommendation were two publications of the results of the Watchman PROTECT AF trial.

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National Institute for Health and Care Excellence (NICE)

The 2014 NICE clinical guidelines regarding management of atrial fibrillation and the prevention of thromboembolism indicated that if anticoagulation is contraindicated or not tolerated then this treatment could be considered.²⁰ The evidence review for the guideline, published as the NICE Interventional Procedure Guidance on percutaneous occlusion of the left atrial appendage in non-valvular atrial fibrillation for the prevention of thromboembolism,²¹ included large RCTs and case series that evaluated the Watchman and the PLAATO device (which is now off-market).

POLICY SUMMARY

Percutaneous Devices

There is clinical rationale that supports the use of the Watchman device for percutaneous left atrial appendage (LAA) closure for the prevention of thromboembolism in patients with non-valvular atrial fibrillation (AF) when anticoagulation therapies are recommended but non-pharmacological alternatives are indicated.

The health plan considers devices that are not FDA-approved to be investigational and not covered. In addition, health care services which lack FDA approval or services which are prescribed against the lawfully marketed proposed use (i.e., and off-label use of the drug/device) are considered investigational and not covered. The only device FDA-approved for percutaneous closure of the left atrial appendage (LAA) is the Watchman. The other percutaneously inserted devices addressed in this medical policy have not been approved for LAA closure/occlusion. Therefore, the use of devices other than the Watchman for percutaneous closure of the LAA is considered investigational and not covered.

Non-Percutaneous Devices

There is insufficient evidence that the use of the AtriClip device is safe and effective at preventing stroke. Large multicenter randomized controlled trials are needed to evaluate the long-term efficacy of this device, ideally in comparison with pharmacological agents or other devices and/or procedures. In addition, no clinical practice guidelines were identified that addressed the use of these types of LAA occlusion devices.

INSTRUCTIONS FOR USE

Company Medical Policies serve as guidance for the administration of plan benefits. Medical policies do not constitute medical advice nor a guarantee of coverage. Company Medical Policies are reviewed annually and are based upon published, peer-reviewed scientific evidence and evidence-based clinical practice guidelines that are available as of the last policy update. The Companies reserve the right to determine the application of Medical Policies and make revisions to Medical Policies at any time. Providers will be given at least 60-days notice of policy changes that are restrictive in nature.

The scope and availability of all plan benefits are determined in accordance with the applicable coverage agreement. Any conflict or variance between the terms of the coverage agreement and Company Medical Policy will be resolved in favor of the coverage agreement.

REGULATORY STATUS

Mental Health Parity Statement

Coverage decisions are made on the basis of individualized determinations of medical necessity and the experimental or investigational character of the treatment in the individual case.

MEDICAL POLICY CROSS REFERENCES

Clinical Trials and Devices (All Lines of Business except Medicare), MED184

REFERENCES

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