Left Atrial Appendage Devices

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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 Company reserves the right to determine the application of medical policies and make revisions to medical policies at any time. 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. 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. In cases where medical necessity is not established by policy for specific treatment modalities, evidence not previously considered regarding the efficacy of the modality that is presented shall be given consideration to determine if the policy represents current standards of care.

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

PLAN PRODUCT AND BENEFIT APPLICATION

☒ **Commercial** ☐ **Medicaid/OHP*** ☐ **Medicare****

*Medicaid/OHP 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.

Left Atrial Appendage Devices: Guideline Note 173

**Medicare Members

This *Company* policy may be applied to Medicare Plan members only when directed by a separate *Medicare* policy. Note that investigational services are considered **"not medically necessary"** for Medicare members.

COVERAGE CRITERIA

I. Percutaneous left atrial appendage (LAA) closure devices (e.g. Watchman, Amplatzer Amulet) may be considered **medically necessary** 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 increased risk for stroke and systemic embolism based on $CHADS_2$ or CHA_2DS_2-VASc score (see Policy Guidelines below for more information on $CHADS_2$ and CHA_2DS_2-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.):
   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. Removal of left atrial appendage devices may be considered **medically necessary** when the device has been thoroughly evaluated and found to be no longer functional and was appropriately placed for medical necessity.

III. Left atrial appendage devices are considered **not medically necessary** when criterion I. or II. above is not met, including but not limited to any of the following (A.-C.):

A. Devices not approved by the FDA for percutaneous LAA closure (see Regulatory Status);
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 Evidence Summary

POLICY CROSS REFERENCES

- Clinical Trials and Devices, MP234

The full Company portfolio of current Medical Policies is available online and can be accessed here.

POLICY GUIDELINES

Risk Stratification Schemes for Ischemic Stroke[1,2]

1. **$CHADS_2$** (Congestive heart failure, Hypertension, Age ≥75 years, Diabetes mellitus, prior Stroke or TIA or thromboembolism [doubled])
2. **CHA_2DS_2-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)

Guidelines from the American Heart Association/American College of Cardiology/Heart Rhythm Society (2019) recommends oral anticoagulants for patients with atrial fibrillation and an elevated CHA2DS2-VASc score of 2 or greater in men or 3 or greater in women.[1]

Guidelines from the American College of Chest Physicians recommend that stroke risk should be assessed using a risk factor based approach, rather than an categorization into low, moderate/high risk strata for patients with atrial fibrillation, recommending the CHA2DS2-VASc scale to initially identify 'low stroke risk' patients who should not be offered antithrombotic therapy to prevent stroke and reduce

mortality.[2] Subsequent to this initial step, for patients with AF, including those with paroxysmal AF, they recommend stroke prevention should be offered to those AF patients with one or more non-sex CHA2DS2-VASc stroke risk factors (score of ≥ 1 in a male or ≥ 2 in a female).[2]

The following tables have been adapted from the 2014 AHA/ACC/HRS Guideline for the Management of Patients With Atrial Fibrillation:[3]

$CHADS_2$ 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

CHA_2DS_2-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

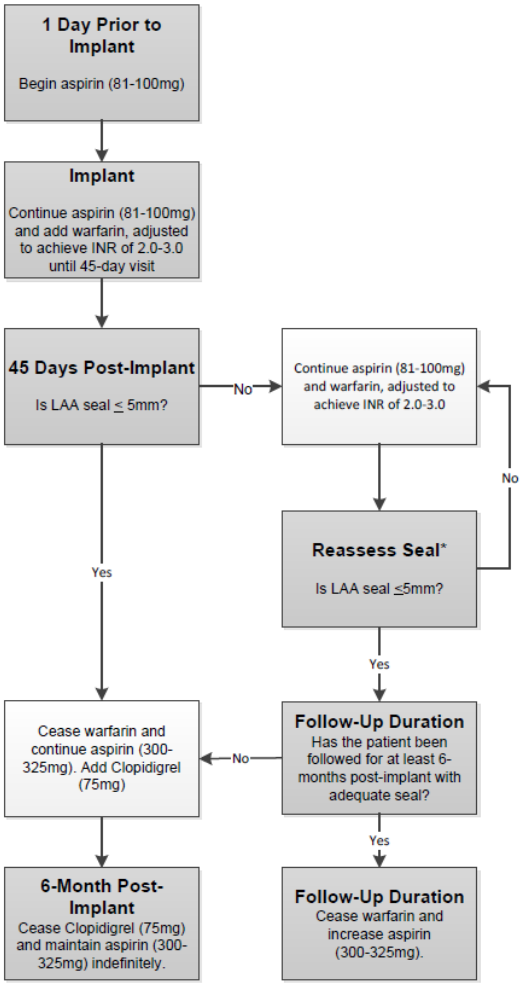
then remain on aspirin 300-325 mg indefinitely. If a patient remains on warfarin and aspirin 81-100 mg for at least 6 months after implantation, and then ceases warfarin, the patient should not require clopidogrel, but should increase to aspirin 300-325 mg daily, which should be taken indefinitely."

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 ≤ 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.**

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."

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."

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.[3] These irregular contractions can lead to the formation of thrombi. Stoke 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 transseptal 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] This device is approved as a 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.

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]

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]

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]

REGULATORY STATUS

U.S. FOOD AND DRUG ADMINISTRATION (FDA)

Approval or clearance by the Food and Drug Administration (FDA) does not in itself establish medical necessity or serve as a basis for coverage. Therefore, this section is provided for informational purposes only.

FDA-Approved Devices

Note: The list of devices below may not be conclusive. Additionally, approved indications and contraindications may change before the policy is annually reviewed. For the most current information of approved devices and supplemental approval order statements, please refer to the U.S. Food and Drug Administration's Premarket Approval (PMA) website (product code: NGV).

Device	Indications	Contraindications
Watchman™ Left Atrial Appendage Closure Technology/ Watchman FLX device (Boston Scientific)[12]	Patients with non-valvular atrial fibrillation who: • Are at increased risk for stroke and systemic embolism based on CHADS2 or CHA2DS2-VASc scores 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 anticoagulation therapy.	• Intracardiac thrombus is present. • An atrial septal defect repair or closure device or a patent foramen ovale repair or closure device is present. • The LAA anatomy will not accommodate a Closure Device. • The patient has a known hypersensitivity to any portion of the device material or the individual components (see Device Description section) such that the use of the WATCHMAN Device or WATCHMAN FLX Device is contraindicated. • Any of the customary contraindications for other percutaneous catheterization procedure (e.g., patient size too small to accommodate TEE probe or required catheters) or conditions (e.g., active infection, bleeding disorder) are present.

		• There are contraindications to the use of anticoagulation therapy, aspirin, or P2Y12 inhibitor.
Amplatzer Amulet® device (St. Jude Medical)[7]	In patients who have nonvalvular atrial fibrillation and who: • Are at increased risk for stroke and systemic embolism based on CHADS2 or CHA2DS2-VASc scores; • Are suitable for short term anticoagulation therapy; • And have appropriate rationale to seek a non-pharmacologic alternative to oral anticoagulation, taking into consideration the safety and effectiveness of the device.	The Amplatzer™ Amulet™ Left Atrial Appendage (LAA) Occluder is contraindicated for patients: • With the presence of intracardiac thrombus • With active endocarditis or other infections producing bacteremia • Where placement of the device would interfere with any intracardiac or intravascular structures
AtriClip® LAA Exclusion System (AtriCure, Inc) [10]	The AtriClip® LAA Exclusion System is indicated for the occlusion of the heart's left atrial appendage, under direct visualization, in conjunction with other open cardiac surgical procedures. 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).	• The safety and effectiveness of this device in atrial rhythm control management, either alone or in combination with ablative treatment, has not been established. • AtriClip placement that allows blood flow into the LAA may not result in complete exclusion and/or electrical isolation.

CLINICAL EVIDENCE AND LITERATURE REVIEW

EVIDENCE REVIEW

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. As such, an evidence review for the Watchman device was not conducted at this time. The health plan considers devices that are not FDA-approved to be not medically necessary and not covered.

Left Atrial Appendage Closure/Occlusion using Surgical Techniques

AtriClip is currently FDA-approved and on the market for LAA occlusion during surgery. 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 2025.

- In 2024, Hayes published an evidence review assessing the safety and efficacy of the AtriClip Left Atrial Appendage (LAA) Exclusion System in patients with atrial fibrillation.[13] In total, 9 studies reported in 10 publications were included for review. One study evaluated the efficacy and safety of AtriClip as a stand-alone procedure in patients for whom oral anticoagulants were contraindicated. In four studies, AtriClip was implanted as an adjunct to thoracoscopic atrial fibrillation ablation or modified maze procedures. Three studies evaluated implantation of AtriClip via sternotomy and as an adjunct procedure to other cardiac surgical procedures including coronary artery bypass graft (CABG), mitral valve repair, mitral valve replacement, tricuspid valve repair, aortic valve replacement, surgical maze procedures, surgical ablation, and aortic dissection. One study evaluated the efficacy of the AtriClip system in eligible patients undergoing either sternotomy, thoracotomy, or thoracoscopy. Across 8 single-arm studies, (rated as "poor" and "very poor" quality), the proportion of patients with complete occlusion of the LAA at final follow up (up to 3.5 years) ranged from 94% to 100%. Complete occlusion was defined as a lack of blood flow into the LAA and absence of a residual stump. Rates of stroke or transient ischemic attack ranged from 0% to 1.7% in studies in which AtriClip was combined with either thoracoscopic AF ablation or cardiac procedures via sternotomy. Rates of antithrombotic medication use varied across all studies ranging from 0% to 43%. No technology-related complications or mortalities were reported. On the basis of the "very low quality" body of evidence, investigators concluded that evidence was insufficient to support the efficacy of the AtriClip system ("D2" rating) as a stand-alone procedure for the prevention of stroke in patients with atrial fibrillation (AF) who are not candidates for oral anticoagulation treatment..

- 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.).[14] 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) [15-18] and small retrospective chart reviews (n=20-24 patients).[19,20] 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 College of Cardiology/Heart Rhythm Society (AHA/ACC/HRS)

In 2019, the AHA/ACC/HRS published a clinical practice guideline addressing the management of patients with atrial fibrillation.[1] Authors made the following recommendations:

"Percutaneous LAA occlusion may be considered in patients with AF at increased risk of stroke who have contraindications to long-term anticoagulation (weak recommendation (Class IIb); nonrandomized evidence (level B-NR))."

"Surgical occlusion of the LAA may be considered in patients with AF undergoing cardiac surgery, as a component of an overall heart team approach to the management of AF (weak recommendation (Class IIb); nonrandomized evidence (level B-NR))."

American College of Chest Physicians

In 2018, the American College of Chest Physicians published an evidence-based expert panel report addressing antithrombotic therapy for atrial fibrillation.[2] Investigators recommended no antithrombotic therapy for patients with AF without valvular heart disease, including those with paroxysmal AF, who are at low risk of stroke (e.g. CHA_2DS_2-VASc [congestive heart failure, hypertension, age $\geq$75 (doubled), diabetes, stroke (doubled)-vascular disease, age 65-74 and sex category (female)] score of 0 in males or 1 in females). For patients with a single non-sex CHA2DS2-VASc stroke risk factor, authors recommended oral anticoagulation rather than no therapy, aspirin, or combination therapy with aspirin and clopidogrel; and for those at high risk of stroke (e.g. CHA_2DS_2-VASc 2 in males or $\geq$ 3 in females), authors recommended oral anticoagulation rather than no therapy, aspirin, or combination therapy with aspirin and clopidogrel.

The Society of Thoracic Surgeons

In 2017, the Society of Thoracic Surgeons published clinical practice guidelines addressing the surgical treatment of atrial fibrillation.[21] On the basis of low-quality evidence, investigators concluded LAA excision or exclusion in conjunction with surgical ablation for AF is reasonable to prevent thromboembolic morbidity (class IIA recommendation, level C evidence [limited data]). Additionally, it was determined to be reasonable to surgically manage the LAA at the time of concurrent cardiac surgery (class IIA recommendation, level C evidence [expert opinion]). This guidance document does not mention specific LAA occlusion devices. Additionally, several authors disclosed relevant conflicts of interest with device manufacturers.

National Institute for Health and Care Excellence (NICE)

In 2021, the NICE published clinical practice guidelines addressing the diagnosis and management of atrial fibrillation. [22] Authors indicated that left atrial appendage occlusion could be considered if anticoagulation is contraindicated or not tolerated. 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,[23] included large RCTs and case series that evaluated the Watchman and the PLAATO device (which is now off-market).

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

The 2014 AHA/ASA joint guidelines regarding primary prevention of stroke recommended the following:[24]

"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 specifically mention the Watchman device, the studies used as a basis for this recommendation were two publications of the results of the Watchman PROTECT AF trial.

EVIDENCE 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.

Devices that are not FDA-approved are considered not medically necessary. 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 not medically necessary. Devices approved by the FDA for percutaneous closure of the left atrial appendage (LAA) may be considered medically necessary. 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 those approved by the FDA for percutaneous closure of the LAA is considered not medically necessary.

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.

HEALTH EQUITY CONSIDERATIONS

The Centers for Disease Control and Prevention (CDC) defines health equity as the state in which everyone has a fair and just opportunity to attain their highest level of health. Achieving health equity requires addressing health disparities and social determinants of health. A health disparity is the occurrence of diseases at greater levels among certain population groups more than among others. Health disparities are linked to social determinants of health which are non-medical factors that influence health outcomes such as the conditions in which people are born, grow, work, live, age, and the wider set of forces and systems shaping the conditions of daily life. Social determinants of health include unequal access to health care, lack of education, poverty, stigma, and racism.

The U.S. Department of Health and Human Services Office of Minority Health calls out unique areas where health disparities are noted based on race and ethnicity. Providence Health Plan (PHP) regularly reviews these areas of opportunity to see if any changes can be made to our medical or pharmacy policies to support our members obtaining their highest level of health. Upon review, PHP creates a Coverage Recommendation (CORE) form detailing which groups are impacted by the disparity, the research surrounding the disparity, and recommendations from professional organizations. PHP Health Equity COREs are updated regularly and can be found online here.

BILLING GUIDELINES AND CODING

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

CODES*		
CPT	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
	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)
	33999	Unlisted procedure, cardiac surgery
HCPCS	C1760	Closure device, vascular (implantable/insertable)
	C2628	Catheter, occlusion

***Coding Notes:**

- The above code list is provided as a courtesy and may not be all-inclusive. Inclusion or omission of a code from this policy neither implies nor guarantees reimbursement or coverage. Some codes may not require routine review for medical necessity, but they are subject to provider contracts, as well as member benefits, eligibility and potential utilization audit.

- All unlisted codes are reviewed for medical necessity, correct coding, and pricing at the claim level. If an unlisted code is submitted for non-covered services addressed in this policy then it will be **denied as not covered**. If an unlisted code is submitted for potentially covered services addressed in this policy, to avoid post-service denial, **prior authorization is recommended**.
- **See the non-covered and prior authorization lists on the Company Medical Policy, Reimbursement Policy, Pharmacy Policy and Provider Information website for additional information.**
- HCPCS/CPT code(s) may be subject to National Correct Coding Initiative (NCCI) procedure-to-procedure (PTP) bundling edits and daily maximum edits known as "medically unlikely edits" (MUEs) published by the Centers for Medicare and Medicaid Services (CMS). This policy does not take precedence over NCCI edits or MUEs. Please refer to the CMS website for coding guidelines and applicable code combinations.

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. *Journal of the American College of Cardiology.* 2019;74(1):104-132
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POLICY REVISION HISTORY

DATE	REVISION SUMMARY
2/2023	Converted to new policy template.
4/2023	Added medical necessity criteria for device removal.
6/2023	Interim update. Change denial from investigational to not medically necessary.
7/2023	Annual update; no changes to criteria or coding. AMPLATZER device removed from list of example devices not approved by the FDA. Added approved devices table.
6/2024	Annual update. No changes to criteria. Title change
6/2025	Annual update. No changes to criteria.
6/2026	Annual update. Re-ordered criteria.
9/2026	Interim update. Unlisted code added to coding table.