

Policy: Percutaneous Left Atrial Appendage Closure Device for Stroke Prevention

Reference Number: PA.CP.MP.147

Effective Date: 01/18

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Coding Implications

Revision Log

Description

Atrial fibrillation (AF) is the most commonly encountered sustained tachyarrhythmia and is associated with a 5-fold increased risk of stroke, and stroke risk increases with age.¹ Among patients with non-valvular AF, the vast majority of thrombus material is located within or involves the left atrial appendage (LAA). Most patients with atrial fibrillation should receive anticoagulant therapy to reduce the risk of systemic embolization. However, not all individuals are candidates for this therapy. LAA occlusion devices have been investigated as an alternative to pharmacological therapy to reduce the risk of stroke in these individuals.

Policy/Criteria

- I. It is the policy of Pennsylvania Health and Wellness[®] (PHW) that Federal Drug Administration (FDA) approved percutaneous devices (i.e. WATCHMAN[™], WATCHMAN FLX[™], and Amplatzer[™] Amulet[™]) for occlusion of the left atrial appendage (LAA) is **medically necessary** to reduce the risk of stroke in adults with non-valvular atrial fibrillation (AF) when both of the following criteria are met:
 - A. There is an increased risk for stroke and systemic embolism based on CHADS₂ or CHA₂DS₂-VASc scores, and long-term anticoagulation therapy is recommended; and
 - B. Contraindications or unacceptable high risk of bleeding from long-term oral anticoagulants, including, but not limited to:
 1. Thrombocytopenia or known coagulation defect associated with bleeding;
 2. Recurrent bleeding, including gastrointestinal, genitourinary, respiratory;
 3. Prior severe bleeding, including intracranial hemorrhage;
 4. Combined use of dual antiplatelet and anticoagulant therapy;
 5. Poor compliance or intolerance with anticoagulant therapy;
 6. High risk of the patient falling or prior falls resulting in injury;
 7. Allergic reactions;
 8. Severe liver disease;
 9. Recent trauma or surgery;
 10. Severe high blood pressure;
 11. Inability to obtain regular international normalized ratios

Note: Warfarin may be required for at least six weeks after implantation of the Watchman or Watchman FLX device.

- II. It is the policy of PHW that current research does not support the use of percutaneous devices other than those noted above for occlusion of the LAA to reduce the risk of stroke in adults with non-valvular AF. There is a paucity of evidence regarding the long-term safety and efficacy of all other percutaneous devices for occlusion of the LAA, and at this time, no other devices are FDA approved for this indication.

Background

The individualized assessment of the risk-benefit balance is central to decision making regarding pharmacotherapy for stroke reduction in atrial fibrillation (AF). To estimate stroke risk, the ACC/American Heart Association/HRS Guideline for the Management of Patients with Atrial Fibrillation recommends the use of the CHA₂DS₂-VASc point score [Congestive heart failure, Hypertension, Age ≥ 75 years (doubled), Diabetes mellitus, prior Stroke, transient ischemic attack, or thromboembolism (doubled), Vascular disease, Age 65 to 74 years, Sex category), which provides an estimate of the potential benefits of therapy. Per the guideline, oral anticoagulation is a class I recommendation for patients with prior stroke, transient ischemic attack (TIA), or a CHA₂DS₂-VASc score ≥ 2 (estimated annual stroke risk of 2.2%) in the context of shared decision making, including a discussion of risks of stroke and bleeding, and the patient's preferences.²

Some patients with AF, whose stroke risk profiles would favor anticoagulation, have relative or absolute contraindications to anticoagulation. Others are unable or unwilling to adhere to long-term anticoagulation therapy. As a result, a number of percutaneous techniques that mechanically prevent embolization of left atrial appendage (LAA) thrombi, often referred to as LAA exclusion procedures, have been studied as an alternative to pharmacological therapy to reduce the risk of stroke. The percutaneous devices include two broad categories: endocardial plug devices to occlude the ostium of the LAA and epicardial LAA ligation procedures to exclude the LAA.

Currently, the WATCHMAN, WATCHMAN FLX, and the Amplatzer Amulet are the only FDA-approved percutaneous LAA closure devices.

The WATCHMAN device is deployed percutaneously via transseptal puncture and has a polyethylene membrane that covers a self-expanding nitinol cage with barbs to anchor the device in the LAA. The early findings for the WATCHMAN device suggest noninferiority to warfarin for the composite endpoint of stroke, systemic embolism, and cardiovascular death; however, early adverse events occur in approximately 10% of patients, including pericardial bleeding. Longer-term follow-up of the WATCHMAN device at 1588 patient-years suggests noninferiority of this device to warfarin.³ A subsequent registry study demonstrated that the WATCHMAN device achieved noninferiority in patients who could not receive warfarin.⁴ Quality of life was assessed in a subset of patients (361 device and 186 warfarin patients) enrolled in the PROTECT AF (Percutaneous Closure of the Left Atrial Appendage Versus Warfarin Therapy for Prevention of Stroke in Patients With Atrial Fibrillation) trial at baseline and 12 months. It was reported that patients with non-valvular AF at risk for stroke, treated with left atrial appendage closure, have favorable quality of life changes at 12 months versus patients treated with warfarin.⁵

The PREVAIL study was mandated by the US FDA to further evaluate the safety profile and confirm the efficacy of the WATCHMAN device for regulatory approval. This study randomly assigned 407 patients in a 2:1 ratio to WATCHMAN or warfarin. Results from the five-year outcomes of the PREVAIL trial and the PROTECT AF trial demonstrated that LAA closure with the WATCHMAN device provided stroke prevention in nonvalvular AF that was comparable to warfarin and included additional reductions in major bleeding and mortality.²²

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The newer-generation WATCHMAN FLX is FDA approved and is widely replacing the WATCHMAN device in most centers.²² The WATCHMAN FLX comes in five sizes with a slightly broader range of dimensions than the WATCHMAN. This device has a distal rounded edge and double row stabilizing anchors, which improves the safety of the procedure.^{22,26} A single-arm prospective registry of 400 patients, the PINNACLE FLX study, concluded that LAA closure with the WATCHMAN FLX device was associated with a low incidence of adverse events and a high incidence of anatomic closure.^{22,26}

The second-generation Amplatzer Cardiac Plug device, the Amulet, received FDA approval in 2021, and includes design advances such as larger lobe size for occluding larger appendages and more stabilizing wires, which improves device stability. A key difference in the Amulet device is the possibility for patients to be discharged without oral anticoagulation immediately after the device has been implanted.²⁷ A multicenter registry report including 1,088 patients showed 99% procedural success with 3.2% of patients having major adverse events.²² The Amulet IDE trial included 1,878 patients with AF who were randomly assigned to receive either the Amulet or WATCHMAN percutaneous LAA occlusion device. Follow up at 18 months showed similar results between the devices with a 2.8% rate of ischemic stroke or systemic embolism.

National Institute for Health and Clinical Excellence (NICE)

Current evidence suggests that percutaneous occlusion of the LAA is efficacious in reducing the risk of thromboembolic complications associated with nonvalvular AF. With regard to safety, there is a risk of life-threatening complications from the procedure, but the incidence of these is low. Therefore, this procedure may be used, provided that normal arrangements are in place for clinical governance, consent and audit.⁷

European Society of Cardiology

Guidelines for the Management of Atrial Fibrillation states LAA occlusion may be considered for stroke prevention in patients with AF and contraindications for long-term anticoagulant treatment. (Class IIb recommendation-usefulness/efficacy is less well established by evidence/opinion.)⁹

American Heart Association/American College of Cardiology/ Heart Rhythm Society

The latest guideline on the management of patients with atrial fibrillation is a 2019 update of the 2014 AHA/ACC/HRS guidelines. This update addresses percutaneous approaches to occlude the LAA and has a new recommendation that percutaneous LAA occlusion may be considered in patients with AF at increased risk of stroke who have contraindications to long-term anticoagulation. FDA approval of the WATCHMAN and clinical trial data necessitated this recommendation.¹

Coding Implications

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included for informational purposes only. Codes referenced in this clinical policy are for informational purposes only. Inclusion or exclusion of any codes does not guarantee coverage. Providers should reference the most up-to-date sources of professional coding guidance prior to the submission of claims for reimbursement of covered services.

CPT® Codes	Description
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

HCPCS Codes	Description
N/A	

ICD-10-CM Diagnosis Codes that Support Coverage Criteria

ICD-10-CM Code	Description
I48.11-148.19	Persistent atrial fibrillation
I48.20-148.21	Chronic atrial fibrillation
I48.91	Unspecified atrial fibrillation

Reviews, Revisions, and Approvals	Revision Date	Approval Date
Clarified in I.A and I.B that the anticoagulation therapy recommended is for “long-term” use. Updated background information to include possible complication associated with the device. Revised information under section “AHA/ACC/HRS” for clarification purposes. References reviewed and updated.	06/18	
References reviewed and updated. Coding reviewed.	10/19	
References reviewed and updated. I48.1 updated to I48.11-I48.19 and I48.2 updated to I48.20-I48.21	10/2020	12/2020
Replaced “investigational” in II with “there is a paucity of evidence regarding the long-term safety and efficacy of all other percutaneous devices for occlusion of the LAA ...” References reviewed and updated. Verbiage edits to I.B, adding contraindications of 1.-11, in addition to the note regarding Warfarin. Annual Review completed, References reviewed/revised, and specialist reviewed.	07/2021	
Annual Review. Updated criteria I and criteria II to include all FDA approved percutaneous devices for occlusion of the LAA (WATCHMAN, WATCHMAN FLX, Amplatzer Amulet) and removed verbiage that the WATCHMAN is the only FDA approved device. Updated background to include information on WATCHMAN FLX and	02/2023	

Reviews, Revisions, and Approvals	Revision Date	Approval Date
Amplatzer Amulet devices with updated notation that both devices are FDA approved and removed verbiage that the WATCHMAN is the only FDA approved device. Updated AHA/ACC/HRS recommendation in background. References reviewed and updated. Changed “Review Date” in policy header to “Date of Last Revision,” and “Date” in the revision log header to “Revision Date.” Specialist reviewed.		

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 in Collaboration With the Society of Thoracic Surgeons [published correction appears in *Circulation*. 2019 Aug 6;140(6):e285]. *Circulation*. 2019;140(2):e125-e151. doi:10.1161/CIR.0000000000000665
2. Masoudi FA, Calkins H, Kavinsky CJ, et al. 2015 ACC/HRS/SCAI left atrial appendage occlusion device societal overview. *Heart Rhythm*. 2015;12(10):e122-e136. doi:10.1016/j.hrthm.2015.06.034
3. Reddy VY, Doshi SK, Sievert H, et al. Percutaneous left atrial appendage closure for stroke prophylaxis in patients with atrial fibrillation: 2.3-Year Follow-up of the PROTECT AF (Watchman Left Atrial Appendage System for Embolic Protection in Patients with Atrial Fibrillation) Trial. *Circulation*. 2013;127(6):720-729. doi:10.1161/CIRCULATIONAHA.112.114389
4. Reddy VY, Möbius-Winkler S, Miller MA, et al. Left atrial appendage closure with the Watchman device in patients with a contraindication for oral anticoagulation: the ASAP study (ASA Plavix Feasibility Study With Watchman Left Atrial Appendage Closure Technology). *J Am Coll Cardiol*. 2013;61(25):2551-2556. doi:10.1016/j.jacc.2013.03.035
5. Reddy VY, Möbius-Winkler S, Miller MA, et al. Left atrial appendage closure with the Watchman device in patients with a contraindication for oral anticoagulation: the ASAP study (ASA Plavix Feasibility Study With Watchman Left Atrial Appendage Closure Technology). *J Am Coll Cardiol*. 2013;61(25):2551-2556. doi:10.1016/j.jacc.2013.03.035
6. National Institute for Health and Care Excellence. Percutaneous occlusion of the left atrial appendage in non-valvular atrial fibrillation for the prevention of thromboembolism - Interventional procedures guidance [IPG349]. <https://www.nice.org.uk/guidance/ipg721/chapter/1-Recommendations>. Published June 23, 2010. Accessed April 27, 2022.
7. U.S. Food and Drug Administration. WATCHMAN Left Atrial Appendage Closure Device with Delivery System and WATCHMAN FLX Left Atrial Appendage Closure Device with Delivery System - P130013/S035. <https://www.fda.gov/medical-devices/recently-approved-devices/watchman-left-atrial-appendage-closure-device-delivery-system-and-watchman-flx-left-atrial-appendage>. Published August 11, 2020. Accessed May 02, 2022.

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8. Kirchhof P, Benussi S, Kotecha D, et al. 2016 ESC Guidelines for the Management of Atrial Fibrillation Developed in Collaboration With EACTS [published correction appears in *Rev Esp Cardiol (Engl Ed)*. 2017 Nov;70(11):1031]. *Rev Esp Cardiol (Engl Ed)*. 2017;70(1):50. doi:10.1016/j.rec.2016.11.033
9. Reddy VY, Holmes D, Doshi SK, Neuzil P, Kar S. Safety of percutaneous left atrial appendage closure: results from the Watchman Left Atrial Appendage System for Embolic Protection in Patients with AF (PROTECT AF) clinical trial and the Continued Access Registry. *Circulation*. 2011;123(4):417-424. doi:10.1161/CIRCULATIONAHA.110.976449
10. Sahay S, Nombela-Franco L, Rodes-Cabau J, et al. Efficacy and safety of left atrial appendage closure versus medical treatment in atrial fibrillation: a network meta-analysis from randomised trials. *Heart*. 2017;103(2):139-147. doi:10.1136/heartjnl-2016-309782
11. Belgaid DR, Khan Z, Zaidi M, Hobbs A. Prospective randomized evaluation of the watchman left atrial appendage closure device in patients with atrial fibrillation versus long-term warfarin therapy: The PREVAIL trial. *Int J Cardiol*. 2016;219:177-179. doi:10.1016/j.ijcard.2016.06.041
12. Price MJ, Reddy VY, Valderrábano M, et al. Bleeding Outcomes After Left Atrial Appendage Closure Compared With Long-Term Warfarin: A Pooled, Patient-Level Analysis of the WATCHMAN Randomized Trial Experience. *JACC Cardiovasc Interv*. 2015;8(15):1925-1932. doi:10.1016/j.jcin.2015.08.035
13. 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;65(24):2614-2623. doi:10.1016/j.jacc.2015.04.025
14. Holmes DR Jr, Kar S, Price MJ, 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 [published correction appears in *J Am Coll Cardiol*. 2014 Sep 16;64(11):1186]. *J Am Coll Cardiol*. 2014;64(1):1-12. doi:10.1016/j.jacc.2014.04.029
15. Bajaj NS, Parashar A, Agarwal S, et al. Percutaneous left atrial appendage occlusion for stroke prophylaxis in nonvalvular atrial fibrillation: a systematic review and analysis of observational studies. *JACC Cardiovasc Interv*. 2014;7(3):296-304. doi:10.1016/j.jcin.2013.11.010
16. Chun KR, Bordignon S, Urban V, et al. Left atrial appendage closure followed by 6 weeks of antithrombotic therapy: a prospective single-center experience. *Heart Rhythm*. 2013;10(12):1792-1799. doi:10.1016/j.hrthm.2013.08.025
17. 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 randomised non-inferiority trial [published correction appears in *Lancet*. 2009 Nov 7;374(9701):1596]. *Lancet*. 2009;374(9689):534-542. doi:10.1016/S0140-6736(09)61343-X
18. Pillarisetti J, Reddy YM, Gunda S, et al. Endocardial (Watchman) vs epicardial (Lariat) left atrial appendage exclusion devices: Understanding the differences in the location and type of leaks and their clinical implications. *Heart Rhythm*. 2015;12(7):1501-1507. doi:10.1016/j.hrthm.2015.03.020

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19. Gloekler S, Shakir S, Doblies J, et al. Early results of first versus second generation Amplatzer occluders for left atrial appendage closure in patients with atrial fibrillation. *Clin Res Cardiol*. 2015;104(8):656-665. doi:10.1007/s00392-015-0828-1
20. Tzikas A, Shakir S, Gafoor S, et al. Left atrial appendage occlusion for stroke prevention in atrial fibrillation: multicentre experience with the AMPLATZER Cardiac Plug. *EuroIntervention*. 2016;11(10):1170-1179. doi:10.4244/EIJY15M01_06
21. Hayes Technology Assessment. Comparative effectiveness review of percutaneous left appendage closure to reduce stroke risk in patients with atrial fibrillation. Published February 13, 2018 (annual review April 30, 2021). Accessed May 02, 2022.
22. Hijazi ZM & Saw J. Atrial fibrillation: Left atrial appendage occlusion. UpToDate. www.uptodate.com. Published November 11, 2021. Accessed April 20, 2022.
23. Reddy VY, Doshi SK, Kar S, et al. 5-Year Outcomes After Left Atrial Appendage Closure: From the PREVAIL and PROTECT AF Trials. *J Am Coll Cardiol*. 2017;70(24):2964-2975. doi:10.1016/j.jacc.2017.10.021
24. Boersma LV, Ince H, Kische S, et al. Evaluating Real-World Clinical Outcomes in Atrial Fibrillation Patients Receiving the WATCHMAN Left Atrial Appendage Closure Technology: Final 2-Year Outcome Data of the EWOLUTION Trial Focusing on History of Stroke and Hemorrhage. *Circ Arrhythm Electrophysiol*. 2019;12(4):e006841. doi:10.1161/CIRCEP.118.006841
25. Hayes Technology Assessment. Left atrial appendage exclusion with the AtriClip system in patients with atrial fibrillation. Hayes. www.hayesinc.com. Published March 11, 2021. Accessed April 27, 2022.
26. Kar S, Doshi SK, Sadhu A, et al. Primary Outcome Evaluation of a Next-Generation Left Atrial Appendage Closure Device: Results From the PINNACLE FLX Trial. *Circulation*. 2021;143(18):1754-1762. doi:10.1161/CIRCULATIONAHA.120.050117
27. Abbott website. Structural Interventions Amplatzer Amulet LAA Occluder. <https://www.structuralheart.abbott/products/laa-closure-device/amplatzer-amulet-laa-occluder>. Accessed May 03, 2022.