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Subject: Percutaneous Left Atrial Appendage Closure Devices for Stroke Prevention in Atrial Fibrillation

THIS MEDICAL COVERAGE GUIDELINE IS NOT AN AUTHORIZATION, CERTIFICATION, EXPLANATION OF BENEFITS, OR A GUARANTEE OF PAYMENT, NOR DOES IT SUBSTITUTE FOR OR CONSTITUTE MEDICAL ADVICE. ALL MEDICAL DECISIONS ARE SOLELY THE RESPONSIBILITY OF THE PATIENT AND PHYSICIAN. BENEFITS ARE DETERMINED BY THE GROUP CONTRACT, MEMBER BENEFIT BOOKLET, AND/OR INDIVIDUAL SUBSCRIBER CERTIFICATE IN EFFECT AT THE TIME SERVICES WERE RENDERED. THIS MEDICAL COVERAGE GUIDELINE APPLIES TO ALL LINES OF BUSINESS UNLESS OTHERWISE NOTED IN THE PROGRAM EXCEPTIONS SECTION.

DESCRIPTION:

Atrial fibrillation is the most common type of irregular heartbeat. Stroke is the most serious complication of atrial fibrillation. Stroke associated with atrial fibrillation is primarily embolic, tends to be more severe than the typical ischemic stroke, and causes higher rates of mortality and disability. As a result, stroke prevention is a main goal of atrial fibrillation treatment.

Stroke in atrial fibrillation occurs primarily as a result of thromboembolism from the left atrium. The lack of atrial contractions in atrial fibrillation leads to blood stasis in the left atrium, and this low flow state increases the risk for thrombosis. The area of the left atrium with the lowest blood flow in atrial fibrillation, and, therefore, the highest risk of thrombosis, is the left atrial appendage (LAA).

The main treatment for stroke prevention in atrial fibrillation is anticoagulation, which has proven efficacy. While anticoagulation is effective for stroke prevention, it carries an increased risk of bleeding. The risk for stroke among individuals with atrial fibrillation is evaluated using several factors. The most common tools are the CHADS2 score and the CHADS2-VASc score.

Percutaneous left atrial appendage closure (LAAC) devices have been developed as a nonpharmacologic alternative to anticoagulation for stroke prevention in atrial fibrillation. The devices may prevent stroke by occluding the LAA, thus preventing thrombus formation.

POSITION STATEMENT:

The use of a device approved by the U.S. Food and Drug Administration (FDA) (eg, the Watchman™; Amplatzer™ Amulet™) for percutaneous left atrial appendage closure **meets the definition of medical**

necessity for the prevention of stroke in individuals with atrial fibrillation when the all of the following criteria are met:

- There is an increased risk of stroke and/or systemic embolism based on CHADS2 score* (≥ 2), or CHA2DS2-VASc score** (≥ 3), and systemic anticoagulation therapy is recommended; **AND**
- The long-term risks of systemic anticoagulation outweigh the risks of the device implantation (HAS-BLED score*** ≥ 3)

The use of other percutaneous left atrial appendage closure devices is considered **experimental or investigational**, including but not limited to the Lariat and Amplatzer™ Cardiac Plug devices. Data in published clinical literature are inadequate to permit scientific conclusions on long-term and net health outcomes.

*CHADS2 Calculator for Atrial Fibrillation

Criteria	Score
Congestive heart failure (any history of CHF or LV dysfunction)	+1
Hypertension (any history of a hypertension diagnosis, regardless of severity)	+1
Age 75 years or older	+1
Diabetes mellitus (any history of a diabetes diagnosis, regardless of severity)	+1
Stroke or TIA (any history of cerebral ischemia)	+2

**CHA2DS2-VASc Calculator for Atrial Fibrillation

Criteria	Score
Congestive heart failure (signs/symptoms of heart failure confirmed with objective evidence of cardiac dysfunction)	+1
Hypertension (resting BP > 140/90 mmHg on at least 2 occasions or current antihypertensive pharmacologic treatment)	+1
Age 75 years or older	+2
Diabetes mellitus (fasting glucose > 125 mg/dL or treatment with oral hypoglycemic agent and/or insulin)	+1
Stroke, TIA, or Thromboembolism (includes any history of cerebral ischemia)	+2
Vascular disease (prior MI, peripheral arterial disease, or aortic plaque)	+1
Age 65 to 74 years	+1
Gender category (female)	+1

***HAS-BLED Calculator for Atrial Fibrillation

Criteria	Score
Hypertension (uncontrolled hypertension (systolic BP > 160 mmHg)	+1
Abnormal renal or liver function [Renal: Chronic dialysis, renal transplant, serum creatinine ≥ 2.3 mg/dL (200 µmol/L)] [Liver: Cirrhosis, bilirubin > 2x UNL with AST/ALT/AP > 3x UNL]	+1 or +2

Stroke	+1
Bleeding (bleeding history or predisposition (anemia)	+1
Labile INR (therapeutic time in range < 60%)	+1
Elderly (greater than 65 years old	+1
Drugs or alcohol [Drugs - other antiplatelet agents or NSAIDs] [Alcohol - more than 8 drinks per week]	+1 or +2

BILLING/CODING INFORMATION:

None applicable.

CPT Coding:

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

REIMBURSEMENT INFORMATION:

Refer to section entitled **POSITION STATEMENT**.

PROGRAM EXCEPTIONS:

Federal Employee Program (FEP): Follow FEP guidelines.

State Account Organization (SAO): Follow SAO guidelines.

Medicare Advantage products: The following National Coverage Determination (NCD) was reviewed on the last guideline reviewed date: Percutaneous LEFT ATRIAL APPENDAGE Closure (LAAC) (20.34), located at cms.gov.

If this Medical Coverage Guideline contains a step therapy requirement, in compliance with Florida law 627.42393, members or providers may request a step therapy protocol exemption to this requirement if based on medical necessity. The process for requesting a protocol exemption can be found at Coverage Protocol Exemption Request.

DEFINITIONS:

None.

RELATED GUIDELINES:

None.

OTHER:

Other names used to report percutaneous left atrial appendage closure devices:

Note: The use of specific product names is illustrative only. It is not intended to be a recommendation of one product over another, and is not intended to represent a complete listing of all products available.

PLAATO device
Lariat Loop Applicator

REFERENCES:

1. Abbott AMPLATZER™ AMULET™ LEFT ATRIAL APPENDAGE OCCLUDER: Important Safety Information. Abbott | 3200 Lakeside Dr. | Santa Clara, CA. | 95054 USA. © 2021 Abbott. www.structuralheart.abbott.
2. AHRQ National Guideline Clearinghouse. Guideline Summary NGC 011175: The Society of Thoracic Surgeons 2017 clinical practice guidelines for the surgical treatment of atrial fibrillation (January 2017).
3. Akca F, et al. Is there an alternative treatment for patients intolerant to antiplatelet therapy if percutaneous left atrial appendage closure is considered? Neth Heart J. 2017 Sep;25(9):510-515.
4. Akin I, Nienaber CA. Left atrial appendage occlusion: A better alternative to anticoagulation? World J Cardiol. 2017 Feb 26;9(2):139-146.
5. Alli O, et al. Quality of life assessment in the randomized PROTECT AF (Percutaneous Closure of the Left Atrial Appendage Versus Warfarin Therapy for Prevention of Stroke in Patients With Atrial Fibrillation) trial of patients at risk for stroke with nonvalvular atrial fibrillation. Journal of the American College of Cardiology [2013, 61 (17):1790-1798].
6. Alipour A, et al. Novel stroke risk reduction in atrial fibrillation: left atrial appendage occlusion with a focus on the Watchman closure device. Vasc Health Risk Manag. 2017 Mar 6;13:81-90.
7. Aryana A, et al. Advances in Left Atrial Appendage Occlusion Strategies. J Atr Fibrillation. 2013 Dec 31;6(4):929.
8. Black-Maier E, Piccini JP, Granger CB. Left atrial appendage closure: A therapy uniquely suited for specific populations of patients with atrial fibrillation. J Cardiovasc Electrophysiol. 2019;30(12):2968–2976. doi:10.1111/jce.14182.
9. Blue Cross Blue Shield Association Evidence Positioning System®. 2.02.26 - Percutaneous Left Atrial Appendage Closure Devices for Stroke Prevention in Atrial Fibrillation, 06/25.
10. Blue Cross and Blue Shield Association Technology Evaluation Center (TEC). Percutaneous left atrial appendage closure therapy for prevention of stroke. TEC Assessments 2014;29; Tab 5.
11. 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.
12. Brouwer TF, Whang W, Kuroki K, Halperin JL, Reddy VY. Net Clinical Benefit of Left Atrial Appendage Closure Versus Warfarin in Patients With Atrial Fibrillation: A Pooled Analysis of the Randomized PROTECT-AF and PREVAIL Studies. J Am Heart Assoc. 2019;8(23):e013525. doi:10.1161/JAHA.119.013525.
13. Centers for Medicare & Medicaid Services (CMS). Decision Memo for Percutaneous Left Atrial Appendage (LAA) Closure Therapy (CAG-00445N). February 8, 2016.

14. Centers for Medicare & Medicaid Services (CMS). National Coverage Determination (NCD) for Percutaneous LEFT ATRIAL APPENDAGE Closure (LAAC) (20.34) (02/08/16).
15. Chung J, et al. Variations in Anticoagulation Practices Following the Maze Procedure. J Atr Fibrillation. 2015 Oct 31;8(3):1273.
16. Cimmino G, Loffredo FS, et al. Percutaneous Left Atrial Appendage Occlusion: An Emerging Option in Patients with Atrial Fibrillation at High Risk of Bleeding. Medicina (Kaunas). 2021 May 3;57(5):444. doi: 10.3390/medicina57050444.
17. Collado FMS, Lama von Buchwald CM, Anderson CK, Madan N, Suradi HS, Huang HD, Jneid H, Kavinsky CJ. Left Atrial Appendage Occlusion for Stroke Prevention in Nonvalvular Atrial Fibrillation. J Am Heart Assoc. 2021 Nov 2;10(21):e022274. doi: 10.1161/JAHA.121.022274. Epub 2021 Oct 20.
18. Ding WY, Gupta D. Percutaneous Left Atrial Appendage Occlusion: A View From the UK. Arrhythm Electrophysiol Rev. 2020 Aug;9(2):83-87. doi: 10.15420/aer.2020.03.
19. Eng L, Saw J. Percutaneous left atrial appendage closure: here to stay. J Thorac Dis. 2016 Sep;8(9):2420-2423.
20. Evora PRB, et al. The Left Atrial Appendage Revised. Braz J Cardiovasc Surg. 2017 Nov-Dec;32(6):517-522.
21. Holmes DR Jr, Doshi SK, Kar S, Price MJ, Sanchez JM, Sievert H, Valderrabano M, Reddy VY. 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.
22. Holmes DR Jr, Korsholm K, Rodés-Cabau J, Saw J, Berti S, Alkhouli MA. Left atrial appendage occlusion. EuroIntervention. 2023 Feb 6;18(13):e1038-e1065. doi: 10.4244/EIJ-D-22-00627.
23. Holmes DR, 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. J Am Coll Cardiol. Jul 8 2014;64(1):1-12.
24. Huang WP, et al. Efficacy and Safety of the WATCHMAN Left Atrial Appendage System for Stroke Prevention in Chinese Patients with Nonvalvular Atrial Fibrillation: A Single-center, Prospective, Observational Study. Chin Med J (Engl). 2017 Feb 20;130(4):434-438.
25. Huang H, Liu Y, et al. Percutaneous Left Atrial Appendage Closure With the LAmbre Device for Stroke Prevention in Atrial Fibrillation: A Prospective, Multicenter Clinical Study. JACC Cardiovasc Interv. 2017 Nov 13;10(21):2188-2194. doi: 10.1016/j.jcin.2017.06.072.
26. January CT, Wann LS, Alpert JS, Calkins H, Cigarroa JE, Cleveland JC Jr, Conti JB, Ellinor PT, Ezekowitz MD, Field ME, Murray KT, Sacco RL, Stevenson WG, Tchou PJ, Tracy CM, Yancy CW. 2014 AHA/ACC/HRS guideline for the management of patients with atrial fibrillation: executive summary: a report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines and the Heart Rhythm Society. J Am Coll Cardiol 2014;64:2246–80.
27. January, CT, Wann, LL, Calkins, HH, Field, MM, Chen, LL, Furie, KK, Cigarroa, JJ, Heidenreich, PP, Cleveland, JJ, Murray, KK, Ellinor, PP, Shea, JJ, Ezekowitz, MM, Tracy, CC, Yancy, CC. 2019 AHA/ACC/HRS Focused Update of the 2014 AHA/ACC/HRS Guideline for the Managemt 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. Heart Rhythm, 2019 Feb 1.
28. Jazayeri MA, et al. Five years of keeping a watch on the left atrial appendage-how has the WATCHMAN fared? J Thorac Dis. 2016 Dec;8(12):E1726-E1733.
29. Lakkireddy D, Thaler D, Ellis CR, et al. Amplatzer Amulet Left Atrial Appendage Occluder Versus Watchman Device for Stroke Prophylaxis (Amulet IDE): A Randomized, Controlled Trial. Circulation. 2021 Nov 9;144(19):1543-1552. doi: 10.1161/CIRCULATIONAHA.121.057063. Epub 2021 Aug 30.
30. Litwinowicz R, Bartus M, Kapelak B, Suwalski P, Lakkireddy D, Lee RJ, Bartus K. Reduction in risk of stroke and bleeding after left atrial appendage closure with LARIAT device in patients with increased

risk of stroke and bleeding: Long term results. Catheterization and cardiovascular interventions: official journal of the Society for Cardiac Angiography & Interventions. 2019 Mar 18. PMID: 30884101.

31. Masoud A, Bartoletti S, et al. Outcome of left atrial appendage occlusion in high-risk patients. Heart. 2018 Apr;104(7):594-599. doi: 10.1136/heartjnl-2017-312383. Epub 2017 Nov 9.
32. Matsuo Y, et al. Interventional closure of the left atrial appendage for stroke prevention. Circ J. 2014;78(3):619-24.
33. Mavroudis C, Deal BJ. Prophylactic arrhythmia surgery in association with congenital heart disease. Transl Pediatr. 2016 Jul;5(3):148-159.
34. National Guideline Clearinghouse. Guideline Summary NGC-10473: Atrial fibrillation: the management of atrial fibrillation. National Clinical Guideline Centre. London (UK): National Institute for Health and Care Excellence (NICE); 2014 Jun.
35. National Institute for Health and Care Excellence (NICE). Interventional Procedure Guidance (IPG) 349: Percutaneous occlusion of the left atrial appendage in non-valvular atrial fibrillation for the prevention of thromboembolism. June 2010. Accessed at http://www.nice.org.uk/guidance/ipg349/.
36. National Institute for Health and Care Excellence (NICE). Interventional Procedure Guidance (IPG) 400: Thoracoscopic exclusion of the left atrial appendage (with or without surgical ablation) for non-valvular atrial fibrillation for the prevention of thromboembolism. June 2011. Accessed at http://www.nice.org.uk/guidance/ipg400/.
37. National Institute for Health and Care Excellence. NICE Guideline: Atrial fibrillation: diagnosis and management. April 2021. Accessed at https://www.nice.org.uk/guidance/ng196/resources/atrial-fibrillation-diagnosis-and-management-pdf-66142085507269.
38. National Institute for Health and Care Excellence. NICE Pathway: Atrial Fibrillation (November 2018). Accessed at https://pathways.nice.org.uk/.
39. Ohtsuka T, et al. Thoracoscopic stand-alone left atrial appendectomy for thromboembolism prevention in nonvalvular atrial fibrillation. J Am Coll Cardiol. 2013 Jul 9;62(2):103-7.
40. Patel MR, Biviano AB. Atrial fibrillation ablation and left appendage closure in heart failure patients. Curr Opin Cardiol. 2015 May;30(3):259-66.
41. Price MJ, Valderrábano M. Left atrial appendage closure to prevent stroke in patients with atrial fibrillation. Circulation. 2014 Jul 8;130(2):202-12.
42. Reddy VY, et al. Percutaneous left atrial appendage closure vs warfarin for atrial fibrillation: a randomized clinical trial. JAMA. 2014 Nov 19;312(19):1988-98.
43. Reddy VY, Doshi SK, et al. 5-Year Outcomes After Left Atrial Appendage Closure: From the PREVAIL and PROTECT AF Trials. J Am Coll Cardiol. 2017 Dec 19;70(24):2964-2975. doi: 10.1016/j.jacc.2017.10.021. Epub 2017 Nov 4.
44. Reddy VY, Möbius-Winkler S, Miller MA, Neuzil P, Schuler G, Wiebe J, Sick P, Sievert H. 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 Jun 25;61(25):2551-6.
45. Romero J, et al. Left Atrial Appendage Closure Devices. Clin Med Insights Cardiol. 2014; 8: 45–52.
46. Rotta Detto Loria J, Desch S, Pöss J, Kirsch K, Thiele H, Sandri M. Percutaneous Left Atrial Appendage Occlusion-Current Evidence and Future Directions. J Clin Med. 2023 Nov 24;12(23):7292. doi: 10.3390/jcm12237292.
47. Sambola A, Radinovic A, Mazzone P. Percutaneous Left Atrial Appendage Occlusion. Cardiology. 2021;146(1):116-118. doi: 10.1159/000511659. Epub 2020 Nov 26.
48. Starck CT, et al. Epicardial left atrial appendage clip occlusion also provides the electrical isolation of the left atrial appendage. Interact Cardiovasc Thorac Surg. 2012 Sep;15(3):416-8.

49. Suradi HS, Hijazi ZM. Left atrial appendage closure: outcomes and challenges. Neth Heart J. 2017 Feb;25(2):143-151.
50. UpToDate. Atrial fibrillation: Left atrial appendage occlusion. 2024. Accessed at uptodate.com.
51. U.S. Food and Drug Administration (FDA). Approval Letter (P130013a) : WATCHMAN LAA Closure Technology. March 2015. Accessed at http://www.accessdata.fda.gov/cdrh_docs/pdf13/p130013a.pdf.
52. U.S. Food and Drug Administration (FDA). Approval Letter (P130013a) : WATCHMAN LAA Closure Technology. March 2015. Accessed at http://www.accessdata.fda.gov/cdrh_docs/pdf13/p130013a.pdf.
53. U.S. Food and Drug Administration (FDA). Approval Order P200049: Amplatzer™ Amulet™ Left Atrial Appendage Occluder. August 2021. Accessed at https://www.accessdata.fda.gov/cdrh_docs/pdf20/P200049A.pdf.
54. Wei Z, ET AL. A meta-analysis for efficacy and safety evaluation of transcatheter left atrial appendage occlusion in patients with nonvalvular atrial fibrillation. Medicine (Baltimore). 2016 Aug;95(31):e4382.
55. You JJ, et al. Antithrombotic therapy for atrial fibrillation: Antithrombotic Therapy and Prevention of Thrombosis, 9th ed: American College of Chest Physicians Evidence-Based Clinical Practice Guidelines. Chest. 2012 Feb;141(2 Suppl):e531S-75S.

COMMITTEE APPROVAL:

This Medical Coverage Guideline (MCG) was approved by the Florida Blue Medical Policy and Coverage Committee on 02/26/26.

GUIDELINE UPDATE INFORMATION:

04/15/16	New Medical Coverage Guideline.
01/01/17	Annual CPT/HCPCS update. Added 33340. Deleted 0281T.
05/15/17	Scheduled review. Position statement maintained. Reformatted guideline. Updated references.
08/15/17	Revision. Added coverage statements for epicardial clipping of the left atrial appendage and left atrial appendectomy. Revised description section and index terms. Updated references.
05/15/18	Scheduled review. Position statement maintained. Updated references.
05/15/19	Scheduled review. Position statement maintained. Updated references.
12/15/19	Revision. Revised MCG title. Updated position statement (coverage statements address LAA percutaneous approach only; deleted epicardial clipping of LAA and left atrial appendectomy coverage statements). Revised index terms and updated references.
05/15/20	Scheduled review. Maintained position statement and updated references.
07/15/21	Scheduled review. Revised CHADS2 score and CHA2DS2-VASc score requirement to ≥ 3. Updated references.
10/15/21	Revision. Added reference to the FDA approved percutaneous Amplatzer™ Amulet™ Left Atrial Appendage Occluder device to the position statement. Updated references.
06/15/22	Revision. Added clarification for Amplatzer™ devices.
11/15/22	Scheduled review. Revised CHADS2 score to ≥ 2. Updated references.
05/25/23	Update to Program Exceptions section.

09/15/24	Scheduled review. Maintained position statement and updated references.
03/15/26	Position statements maintained.