



Subject: Percutaneous Left Atrial Appendage Closure Procedures*

Effective Date: September 29, 2015

Department: Utilization Management

Policy: Percutaneous left atrial appendage closure to reduce stroke risk in patients with atrial fibrillation is reimbursable under Plans administered by QualCare, Inc., for the device specified below.

Objective: To assure proper and consistent reimbursement and to limit application of percutaneous left atrial appendage closure to the device and population in which efficacy is supported by peer-reviewed literature.

Procedure: A. Percutaneous left atrial appendage closure using the Watchman™ device [CPT-0281T; 33340], to reduce stroke/embolism risk is reimbursable when ALL of the following criteria are met:

- 1) The diagnosis is atrial fibrillation, **ICD-9 427.31, ICD 10- I48.0-I48.2, I48.91**, without valvular heart disease.
- 2) The member has a CHADS2 or CHA2DS2-VASc score of 2 or greater (see note below), reflecting increased risk of stroke or embolism.

- 3) The requesting provider deems the member suitable for warfarin anticoagulation therapy(ie there are no absolute contraindications to warfarin anticoagulation therapy)
- 4) The requesting physician documents an appropriate rationale to use a non-pharmacologic alternative to warfarin, considering the safety and effectiveness of the Watchman™ device compared to warfarin.

All requests for percutaneous left atrial appendage closure require medical director review.

B. Any other device used for percutaneous left atrial appendage closure is considered investigational, experimental or unproven due to insufficient published peer-reviewed literature that supports safety and efficacy, including but not limited to:

- 1) Amplatzer® septal closure device
- 2) Amplatzer Amulet® device
- 3) Lariat® Loop Applicator device
- 4) Cardioblate® closure device

Note: The CHADS2 score assigns one point each for the presence of congestive heart failure, hypertension, age ≥ 75 years, diabetes, or prior stroke or transient ischemic attack. TheCHA2DS2-VASc score includes sex, additional age categories, and the presence of vascular disease, in addition to the risk factors used in the CHADS2 score.

References

Boersma LV, Ince H, Kische S, Pokushalov E, et al. Efficacy and safety of left atrial appendage closure with WATCHMAN in patients with or without contraindication to oral anticoagulation: 1-Year follow-up outcome data of the EWOLUTION trial. *Heart Rhythm*. 2017 May 31. pii: S1547-5271(17)30715-4. doi: 10.1016/j.hrthm.2017.05.038. [Epub ahead of print]

Sahay S, Nombela-Franco L, Rodes-Cabau J, Jimenez-Quevedo P, 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(Jan)

Hayes Medical Technology Directory- Percutaneous Left Atrial Appendage Closure to Reduce Stroke Risk in Patients with Atrial Fibrillation. Publication date July 2,2015; annual review-June 15, 2017.

Noelck N, Papak J, Freeman M, Paynter R, et al. The Effectiveness of Procedures to Remove or Occlude the Left Atrial Appendage: A Systematic Review of the Evidence [Internet]. Washington (DC): Department of Veterans Affairs (US); 2015 Oct. VA Evidence-based Synthesis Program Reports.

Bajaj NS, Gaba S, Arora P, et al. Meta-analysis of randomized control trials (RCTS) comparing percutaneous left atrial appendage (Watchman Device) closure versus adjusted dose warfarin for stroke prophylaxis in non-valvular atrial fibrillation. *J Am Coll Cardiol*. 2015; 65(10_S): doi:10.1016/S0735-1097(15)60365-5.

Bode WD, Patel N, Gehi AK. Left atrial appendage occlusion for prevention of stroke in nonvalvular atrial fibrillation: a meta-analysis. *J Interv Card Electrophysiol*. 2015;43(1):79-89

Alli O, Holmes D Jr. Left atrial appendage occlusion. *Heart*. 2015;101(11):834-841

Holmes DR, Doshi SK, Kar S, Price MJ, 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):2614-23(Jun)

Stone D, Byrne T, Pershad A. Early Results With the LARIAT device for left atrial appendage exclusion in patients with atrial fibrillation at high risk for stroke and anticoagulation. *Catheter Cardiovasc Interv*. 2015;86(1):121-127.

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. *J Am Coll Cardiol*. 2014 8;64(1):1-12(Jul)

Reddy VY, Sievert H, Halperin J, et al. Percutaneous left atrial appendage closure vs warfarin for atrial fibrillation: a randomized clinical trial. *JAMA*. 2014;312(19):1988-1998(Nov)

January CT, Wann LS, Alpert JS, et al. 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 practice guidelines and the Heart Rhythm Society. *Circulation*. 2014a;130(23):e199-e267.

January CT, Wann L, Alpert JS, et al. 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(21):2246-2280.

Price MJ, Gibson DN, Yakubov SJ, et al. Early safety and efficacy of percutaneous left atrial appendage suture ligation: results from the U.S. transcatheter LAA ligation consortium. *J Am Coll Cardiol*. 2014;64(6):565-572.

Miller MA, Gangireddy SR, Doshi SK, et al. Multicenter study on acute and long-term safety and efficacy of percutaneous left atrial appendage closure using an epicardial suture snaring device. *Heart Rhythm*. 2014;11(11):1853-1859

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):720-9(Feb)

Alli, O, Doshi, S, Kar, S, 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. *J Am Coll Cardiol*. 2013 30;61(17):1790-8(Apr)

Reddy, VY, Mobius-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):2551-6(Jun)

Urena M, Rodés-Cabau J, Freixa X, et al. Percutaneous left atrial appendage closure with the AMPLATZER cardiac plug device in patients with nonvalvular atrial fibrillation and contraindications to anticoagulation therapy. *J Am Coll Cardiol*. 2013;62(2):96-102.

Price MJ, Valderrábano M. Left atrial appendage closure to prevent stroke in patients with atrial fibrillation. *Circulation*. 2014;130(2):202-212.

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. *Lancet*. 2009;374 (9689):534-42(Aug)

Drafted By/Date: M.McNeil, MD 09/11/15
Approved By/Date: QM Committee 9/29/15
Reviewed w/o revision By/Date: MMcNeil, MD 08/31/17
Approved By/Date: QMC, 10/17/17

*Consistent with Summary Plan Description (SPD). When there is discordance between this policy and the SPD, the provisions of the SPD prevail.