

PERCUTANEOUS LEFT ATRIAL APPENDAGE CLOSURE

Effective Date: November 29, 2017

Review Dates: 2/13, 2/14, 2/15, 2/16, 2/17, 8/17, 2/18, 2/19

Date Of Origin: February 13, 2013

Status: Current

I. POLICY/CRITERIA

Commercial

A. Percutaneous Left Atrial Appendage Closure with an FDA-approved device (e.g. Watchman) is a covered benefit for stroke risk reduction in patients with atrial fibrillation when **all** of the following are met:

1. Paroxysmal, persistent or permanent non-valvular atrial fibrillation (AF) or previous history of non-valvular AF
2. Both of the following risk stratification scores:
 - a. $CHA_2DS_2VAsC \geq 3^*$, AND
 - b. HAS-BLED score $\geq 3^{**}$
3. One of the following:
 - a. Contraindication to long-term oral anticoagulants (OAC) due to a history of internal or external bleeding
 - i. Neurological: intracranial or spinal bleeding (subdural, subarachnoid, parenchymal, intraocular bleeding)
 - ii. GI: diverticulosis, ulcerative colitis, Crohn's disease, recurrent gastric or duodenal ulcer, erosive gastritis, esophageal tears, AV malformations, frequent nose bleeds
 - iii. Urological: hemorrhagic cystitis, urolithiasis with recurrent bleeding
 - iv. Pulmonary: hemoptysis, bronchiectasis, arterial-venous malformations
 - v. Ob-gyn: hypermenorrhea
 - b. Contraindication to long-term OAC due to high risk for bleeding
 - i. Recurrent syncope and falls
 - ii. High-risk occupations (professional athletes, soldiers, divers)
 - iii. Intracranial aneurysms
 - iv. Fixed malignant hypertension
 - v. Thrombocytopenia
 - vi. Dual antiplatelet therapy with high bleeding risk score
 - c. Failure of OAC (e.g. embolic event despite anticoagulation)
 - d. Intolerance or difficulty in using OAC (e.g. unable to obtain INR or $TTR < 60\%$, bleeding or significant side effects of OAC)

4. Survival expectancy >2 years
 5. A formal shared decision making interaction with an independent non-interventional physician using an evidence-based decision tool (*see reference below) on oral anticoagulation in patients with non-valvular atrial fibrillation (NVAF) prior to left atrial appendage closure (LAAC). Additionally, the shared decision making interaction must be documented in the medical record.
 6. None of the following contraindications:
 - a. Contraindicated/allergic to aspirin
 - b. Unable to take aspirin or warfarin for 45 days
 - c. History of atrial septal repair or has an ASD/PFO device
 - d. Implanted mechanical valve prosthesis
 - e. Anticoagulation required for another indication (e.g. DVT, PE)
 - f. LVEF < 20%
 - g. Existing pericardial effusion > 2mm
 7. Prior authorization by Priority Health.
- B. Percutaneous Left Atrial Appendage Closure with non-FDA-approved devices or other procedures (e.g. LARIAT) are considered experimental and investigational and not a covered benefit. Published data are insufficient to determine safety and efficacy of the LARIAT procedure or non-FDA-approved devices.

*Evidence based decision tools

Priority Health accepts the following tools:

1. Ottawa Decision Aids / Ottawa Hospital Research Institute @ <https://decisionaid.ohri.ca/index.html>, atrial fibrillation/anticoagulation aids @ <https://decisionaid.ohri.ca/AZsearch.php?criteria=atrial+&search=Go>
2. EMMI shared decision making @ <https://www.my-emmi.com/SelfReg/PHANTICOAG>

Medicaid

~~This procedure is not covered for Medicaid members.~~

Medicare

1. Patients must meet CMS criteria stated in the National Coverage Determination (NCD) with Coverage with Evidence Development (CED) coverage.
2. Under CED “Medicare covers items and services on the condition that they are furnished in the context of approved clinical studies or with the collection of

additional clinical data. In making coverage decisions involving CED, CMS decides after a formal review of the medical literature to cover an item or service only in the context of an approved clinical study or when additional clinical data are collected to assess the appropriateness of an item or service for use with a particular beneficiary." See Guidance for the Public, Industry, and CMS Staff: Coverage with Evidence Development for more information.

3. Approved CED studies are posted on the CMS Coverage with Evidence Development webpage.

II. MEDICAL NECESSITY REVIEW

Required Not Required Not Applicable

III. APPLICATION TO PRODUCTS

Coverage is subject to member's specific benefits. Group specific policy will supersede this policy when applicable.

- ❖ **HMO/EPO:** *This policy applies to insured HMO/EPO plans.*
- ❖ **POS:** *This policy applies to insured POS plans.*
- ❖ **PPO:** *This policy applies to insured PPO plans. Consult individual plan documents as state mandated benefits may apply. If there is a conflict between this policy and a plan document, the provisions of the plan document will govern.*
- ❖ **ASO:** *For self-funded plans, consult individual plan documents. If there is a conflict between this policy and a self-funded plan document, the provisions of the plan document will govern.*
- ❖ **INDIVIDUAL:** *For individual policies, consult the individual insurance policy. If there is a conflict between this medical policy and the individual insurance policy document, the provisions of the individual insurance policy will govern.*
- ❖ **MEDICARE:** *Coverage is determined by the Centers for Medicare and Medicaid Services (CMS); if a coverage determination has not been adopted by CMS, this policy applies.*
- ❖ **MEDICAID/HEALTHY MICHIGAN PLAN:** *For Medicaid/Healthy Michigan Plan members, this policy will apply. Coverage is based on medical necessity criteria being met and the appropriate code(s) from the coding section of this policy being included on the Michigan Medicaid Fee Schedule located at: http://www.michigan.gov/mdch/0,1607,7-132-2945_42542_42543_42546_42551-159815--,00.html. If there is a discrepancy between this policy and the Michigan Medicaid Provider Manual located at: http://www.michigan.gov/mdch/0,1607,7-132-2945_5100-87572--,00.html, the Michigan Medicaid Provider Manual will govern. For Medical Supplies/DME/Prosthetics and Orthotics, please refer to the Michigan Medicaid Fee Schedule to verify coverage.*

IV. DESCRIPTION

Atrial fibrillation (AF) is an increasingly common condition that carries a significant risk of stroke. Warfarin is the mainstay agent for stroke prevention in AF, although new drugs for this indication have recently entered the U.S. market. Despite newly available drug alternatives to warfarin, an estimated 30% to 50% of AF patients still do not

receive anticoagulation due to contraindications, concerns about lifetime risk for major bleeding, or treatment adherence barriers. For these reasons, nonpharmacologic alternatives to warfarin are in demand.

Percutaneous occlusion of the left atrial appendage (LAA) is among the more promising emerging approaches for stroke prevention in AF. The LAA is a sac-like remnant of the embryonic left atrium, and the site where approximately 90% of clots originate in patients with nonvalvular AF. Excluding the LAA from circulation, therefore, may reduce the risk of stroke in this patient population.

The CHADS₂ [cardiac failure, hypertension, age, diabetes, stroke (doubled)] risk index evolved from the AF Investigators and Stroke Prevention in Atrial Fibrillation (SPAF) Investigators criteria, and is based on a point system in which 2 points are assigned for a history of stroke or TIA and 1 point each is assigned for age >75 years, a history of hypertension, diabetes, or recent cardiac failure. There is a clear relationship between CHADS₂ score and stroke rate. The original validation of this scheme classified a CHADS₂ score of 0 as low risk, 1–2 as moderate risk, and >2 as high risk.

*** CHA₂DS₂-VASc Scoring**

Risk factor-based approach expressed as a point based scoring system, with the acronym CHA₂DS₂-VASc	
<i>(Note: maximum score is 9 since age may contribute 0, 1, or 2 points)</i>	
Risk Factor	Score
Congestive heart failure/LV dysfunction	1
Hypertension	1
Age ≥75	2
Diabetes mellitus	1
Stroke/TIA/thrombo-embolism	2
Vascular disease	1
Age 65–74	1
Sex category (i.e. female sex)	1
Maximum score	9

Adjusted stroke rate according to CHA₂DS₂-VASc score		
CHA₂DS₂-VASc score	Patients (n = 73,538)	Stroke and Thromboembolism event rate at one-year follow-up (%)
0	6,369	0.78

1	8,203	2.01
2	12,771	3.71
3	17,371	5.92
4	13,887	9.27
5	8,942	15.26
6	4,244	19.74
7	1,420	21.50
8	285	22.38
9	46	23.64

**HAS-BLED bleeding risk		
Hypertension History	Uncontrolled, >160 mmHg systolic	1
Renal Disease	Dialysis, transplant, Cr >2.6 mg/dL or >200 μmol/L	1
Stroke History	Focal neuro deficit diagnosed by a neurologist lasting >24 hours caused by intracranial hemorrhage	1
Liver Disease	Cirrhosis or Bilirubin >2x Normal or AST/ALT/AP >3x Normal	1
Labile INR	Unstable/high INRs, Time in Therapeutic Range < 60%	1
Age > 65		1
Medication Usage Predisposing to Bleeding	Antiplatelet agents, NSAIDs	1
Alcohol or Drug Usage History	Current alcohol excess > 8 drinks/week where drink is defined as 12 Fl oz. (350ml) beer 5% alcohol, 5 Fl oz. (150ml) wine 12% alcohol, 1.5 Fl oz. (45ml) 80 proof distilled spirits 40% alcohol	1
Prior Major Bleeding or Predisposition to Bleeding	Prior hemorrhage requiring hospitalization or transfusion, or drop in Hemoglobin >2g/L	1

Published data are insufficient to determine the safety and efficacy of the Lariat procedure or to support use of this procedure as an alternative to oral anticoagulation for stroke prevention in patients with AF. There are no randomized controlled trials comparing the Lariat procedure with other interventions or oral anticoagulation alone. There is a paucity of long-term follow-up data addressing the durability of LAA closure.

Inconsistent long-term TEE follow-up precludes analysis of post procedural clot formation risk. The best available evidence is short-term, low-quality, and inconclusive. The 10% incidence of major procedural complications (bleeding, perforation) reported in the largest U.S. trial is concerning. Interpretation of the best published studies is clouded by the fact that 23% to 55% of patients remained on oral anticoagulants after undergoing the Lariat procedure. Continued use of anticoagulants limits understanding of procedure suitability in patients who cannot take warfarin. An observational study (NCT01695564) comparing the Lariat device to the Watchman device has been completed. The trial began in May 2012 and was to enroll 150 patients; study was completed February 2018 (no study results posted). Data from published trials may guide design of a randomized controlled trial evaluating the safety, efficacy, and durability of the Lariat procedure. (Hayes, Inc. March 2015)

V. CODING INFORMATION

ICD-10 Codes that may apply:

- I48.0 Paroxysmal atrial fibrillation
- I48.1 Persistent atrial fibrillation
- I48.2 Chronic atrial fibrillation
- I48.91 Unspecified atrial fibrillation

CPT/HCPCS Codes:

- 33340 Percutaneous transcatheter closure of the left atrial appendage with endocardial implant, including fluoroscopy, transeptal puncture, catheter placement(s), left atrial angiography, left atrial appendage angiography, when performed, and radiological supervision and interpretation

Not Covered

- 33999 Unlisted procedure, cardiac surgery (*When billed for not covered procedures, explanatory notes must accompany claim.*)

VI. REFERENCES

1. Guidelines for the management of atrial fibrillation. The Task Force for the Management of Atrial Fibrillation of the European Society of Cardiology (ESC) European Heart Journal (2010) 31, 2369–2429
2. 2016 European Society of Cardiology (ESC) Guidelines for the management of atrial fibrillation developed in collaboration with the European Heart Rhythm Association (EACTS) Management of Atrial Fibrillation 2016 @ <http://www.escardio.org/Guidelines/Clinical-Practice-Guidelines/Atrial-Fibrillation-Management#> (Retrieved January 4, 2017 & January 8, 2019).
3. Watchman® Left Atrial Appendage Closure Technology, Hayes Prognosis Overview, July 2012 & December 2013.

4. 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 Feb 1; 123(4):417-24. Epub 2011 Jan 17.
5. Hayes, Inc. Percutaneous Left Atrial Appendage Closure to Reduce Stroke Risk in Patients with Atrial Fibrillation, January 2, 2013 & January 24, 2014
6. Hayes, Inc. Lariat Suture Delivery Device Prognosis Overview, November 13, 2014.
Gregory Y. H. Lip, MD; Robby Nieuwlaat, PhD; Ron Pisters, MD; Deirdre A. Lane, PhD; Harry J. G. M. Crijns, MD Refining Clinical Risk Stratification for Predicting Stroke and Thromboembolism in Atrial Fibrillation Using a Novel Risk Factor-Based Approach: The Euro Heart Survey on Atrial Fibrillation *Chest*. 2010; 137(2):263-272.
<http://journal.publications.chestnet.org/article.aspx?articleid=1086288&resultClick=1> (Retrieved January 4, 2017 & January 8, 2019)
7. Hayes, Inc. Percutaneous Left Atrial Appendage Closure to Reduce Stroke Risk in Patients with Atrial Fibrillation, July 2015 and annual updates 2016 & 2017
8. Hayes, Inc. Lariat Suture Delivery Device, March 2015
9. HAS-BLED @ <http://www.mdcalc.com/has-bleed-score-for-major-bleeding-risk/>
10. Pisters R(1), Lane DA, Nieuwlaat R, de Vos CB, Crijns HJ, Lip GY. A novel user-friendly score (HAS-BLED) to assess 1-year risk of major bleeding in patients with atrial fibrillation: the Euro Heart Survey. *Chest*. 2010 Nov; 138(5):1093-100.
11. National Institutes of Health: Rethinking Drinking What counts as a drink? @ <http://rethinkingdrinking.niaaa.nih.gov/How-much-is-too-much/what-counts-as-a-drink/whats-A-Standard-drink.aspx> (Retrieved January 8, 2019).
12. 2012 focused update of the ESC Guidelines for management of AF. *Eur Heart J* 2012; 33:2719
13. CMS Decision Memo for Percutaneous Left Atrial Appendage (LAA) Closure Therapy (CAG-00445N) February 8, 2016 @ <https://www.cms.gov/medicare-coverage-database/details/nca-decision-memo.aspx?NCAId=281&bc=AAAAAAAAAgAAAA%3d%3d&>
14. Nonpharmacologic therapy to prevent embolization in patients with atrial fibrillation. UpToDate. @ https://www.uptodate.com/contents/nonpharmacologic-therapy-to-prevent-embolization-in-patients-with-atrial-fibrillation?source=search_result&search=watchman&selectedTitle=1~1 (Retrieved January 4, 2017 & January 8, 2019).
15. CMS Percutaneous Left Atrial Appendage Closure Coverage with Evidence Development @ <https://www.cms.gov/Medicare/Coverage/Coverage-with-Evidence-Development/LAAC.html> (accessed January 9, 2018 & January 8, 2019)

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