PriorityHealth

MEDICAL POLICY
No. 91605-R2

PERCUTANEOUS LEFT ATRIAL APPENDAGE CLOSURE

Effective Date: November 29, 2017
Date Of Origin: February 13, 2013
Review Dates: 2/13, 2/14, 2/15, 2/16, 2/17, 8/17, 2/18
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 ≥ 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 $CHADS_2$ [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 $CHADS_2$ score and stroke rate. The original validation of this scheme classified a $CHADS_2$ score of 0 as low risk, 1–2 as moderate risk, and >2 as high risk.

*** CHA_2DS_2-VASc Scoring**

Risk factor-based approach expressed as a point based scoring system, with the acronym CHA_2DS_2-VASc (Note: maximum score is 9 since age may contribute 0, 1, or 2 points)	
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 CHA_2DS_2-VASc score		
CHA_2DS_2-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 postprocedural 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 is ongoing. The trial began in May 2012 and is enrolling 150 patients; preliminary results are not expected until 2017. 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

CPT/HCPCS Codes:

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

Not Covered

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

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2. 2016 European Society of Cardiology (ESC) Guidelines for the management of atrial fibrillation developed in collaboration with the European Hearth Rhythm Association (EACTS) Management of Atrial Fibrillation 2016 @ http://www.escardio.org/Guidelines/Clinical-Practice-Guidelines/Atrial-Fibrillation-Management# (Retrieved January 4, 2017).

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12. 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
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