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Reviewed: 10/27/22

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Next Review: 10/26/23

## 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.

<a href="#">Position Statement</a>	<a href="#">Billing/Coding</a>	<a href="#">Reimbursement</a>	<a href="#">Program Exceptions</a>	<a href="#">Definitions</a>	<a href="#">Related Guidelines</a>
<a href="#">Other</a>	<a href="#">References</a>	<a href="#">Updates</a>			

### 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\* ( $\geq 2$ ), or CHA2DS2-VASc score\*\* ( $\geq 3$ ), and systemic anticoagulation therapy is recommended; **AND**
- The long-term risks of systemic anticoagulation outweigh the risks of the device implantation (HAS-BLED score\*\*\*  $\geq 3$ )

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

#### \*\*CHA2DS2-VASc Calculator for Atrial Fibrillation

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

#### \*\*\*HAS-BLED Calculator for Atrial Fibrillation

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

<b>Stroke</b>	+1
<b>Bleeding</b> (bleeding history or predisposition (anemia))	+1
<b>Labile INR</b> (therapeutic time in range < 60%)	+1
<b>Elderly</b> (greater than 65 years old)	+1
<b>Drugs or alcohol</b> [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, transeptal puncture, catheter placement(s), left atrial angiography, left atrial appendage angiography, when performed, and radiological supervision and interpretation
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### 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:

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### COMMITTEE APPROVAL:

This Medical Coverage Guideline (MCG) was approved by the Florida Blue Medical Policy and Coverage Committee on 10/27/22.

### 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 $\geq 3$ . 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 $\geq 2$ . Updated references.
05/25/23	Update to Program Exceptions section.