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Medical policies in conjunction with other nationally recognized standards of care are used to make medical coverage decisions.

Percutaneous Left Atrial Appendage Closure (LAAC) Policy

Indication/Usage:

The left atrial appendage (LAA) is a tubular structure that opens into the left atrium and has been shown to be one potential source for blood clots that can cause strokes due to migration of clots that may form in the LAA. Patients with atrial fibrillation (AF), are at an increased risk of stroke. While thinning the blood with anticoagulant medications has been proven to prevent strokes, percutaneous LAA closure (LAAC) has been studied as a non-pharmacologic alternative for patients with atrial fibrillation.

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Medical Indications for Authorization Commercial Members

SummaCare considers Left Atrial Appendage Closure devices medically necessary for nonvalvular atrial fibrillation (NVAF) when the device has received Food and Drug Administration (FDA) Premarket Approval (PMA) for that device's FDA-approved indication and meet ALL of the conditions specified below

1. A CHADS2 score ≥ 2 (Congestive heart failure, Hypertension, Age> 75, Diabetes, Stroke/transient ischemia attack/thromboembolism) or CHA2DS2-VASc score ≥ 3 (Congestive heart failure, Hypertension, Age ≥ 65, Diabetes, Stroke/transient ischemia attack/ thromboembolism, Vascular disease, Sex category).

2. A formal shared decision making interaction with an independent non-interventional physician using an evidence-based decision tool on oral anticoagulation in patients with NVAF prior to LAAC. Additionally, the shared decision making interaction must be documented in the medical record.

3. A suitability for short-term warfarin but deemed unable to take long term oral anticoagulation following the conclusion of shared decision making, as LAAC is only covered as a second line therapy to oral anticoagulants. The patient (Preoperatively and postoperatively) is under the care of a cohesive multidisciplinary team (MDT) of medical professionals. The procedure must be furnished in a hospital with an established structural heart disease (SHD) and/or electrophysiology (EP) program.

4. The procedure must be performed by an interventional cardiologist(s), electrophysiologist(s) or cardiovascular surgeon(s) that meet the following criteria:

    - Has received training prescribed by the manufacturer on the safe and effective use of the device prior to performing LAAC; and
    - Has performed ≥ 25 interventional cardiac procedures that involve transeptal puncture through an intact septum; and
    - Continues to perform ≥ 25 interventional cardiac procedures that involve transeptal puncture through an intact septum, of which at least 12 are LAAC, over a two year period.

The patient is enrolled in, and the MDT and hospital must participate in a prospective, national, audited registry that: 1) consecutively enrolls LAAC patients and 2) tracks the following annual outcomes for each patient for a period of at least four years from the time of the LAAC:

- Operator-specific complications
- Device-specific complications including device thrombosis
- Stroke, adjudicated, by type
- Transient Ischemic Attack (TIA)
- Systemic embolism
- Death
- Major bleeding, by site and severity

Definition and scores for $CHADS_2$ and CHA_2DS_2-VASc	
$CHADS_2$ acronym[1]	Score
Congestive HF	1
Hypertension	1
Age ≥75 years	1
Diabetes mellitus	1
Stroke/TIA/TE	2
Maximum score	6

CHA_2DS_2-VASc acronym[2]	Score
Congestive HF	1
Hypertension	1
Age ≥75 years	2
Diabetes mellitus	1
Stroke/TIA/TE	2
Vascular disease (prior MI, PAD, or aortic plaque)	1
Age 65 to 74 years	1
Sex category (ie, female sex)	1
Maximum score	9

Medicare Members

NCD ID 20.34 Percutaneous Left Atrial Appendage Closure (LAAC)

A. General

Patients with atrial fibrillation (AF), an irregular heartbeat, are at an increased risk of stroke. The left atrial appendage (LAA) is a tubular structure that opens into the left atrium and has been shown to be one potential source for blood clots that can cause strokes. While thinning the blood with anticoagulant medications has been proven to prevent strokes, percutaneous LAA closure (LAAC) has been studied as a non-pharmacologic alternative for patients with AF.

Indications and Limitations of Coverage

B. Nationally Covered Indications

The Centers for Medicare & Medicaid Services (CMS) covers percutaneous LAAC for non-valvular atrial fibrillation (NVAF) through Coverage with Evidence Development (CED) with the following conditions:

- LAAC devices are covered when the device has received Food and Drug Administration (FDA) Premarket Approval (PMA) for that device's FDA-approved indication and meet all of the conditions specified below:

The patient must have:

- A CHADS2 score ≥ 2 (Congestive heart failure, Hypertension, Age > 75, Diabetes, Stroke/transient ischemia attack/thromboembolism) or CHA2DS2-VASc score ≥ 3 (Congestive heart failure, Hypertension, Age ≥ 65, Diabetes, Stroke/transient ischemia attack/thromboembolism, Vascular disease, Sex category)
- A formal shared decision making interaction with an independent non-interventional physician using an evidence-based decision tool on oral anticoagulation in patients with NVAF prior to LAAC. Additionally, the shared decision making interaction must be documented in the medical record.
- A suitability for short-term warfarin but deemed unable to take long-term oral anticoagulation following the conclusion of shared decision making, as LAAC is only covered as a second line therapy to oral anticoagulants. The patient (preoperatively and postoperatively) is under the care of a cohesive, multidisciplinary team (MDT) of medical professionals. The procedure must be furnished in a hospital with an established structural heart disease (SHD) and/or electrophysiology (EP) program.

The procedure must be performed by an interventional cardiologist(s), electrophysiologist(s), or cardiovascular surgeon (s) that meet the following criteria:

- Has received training prescribed by the manufacturer on the safe and effective use of the device prior to performing LAAC; and,
- Has performed ≥ 25 interventional cardiac procedures that involve transeptal puncture through an intact septum; and,
- Continues to perform ≥ 25 interventional cardiac procedures that involve transeptal puncture through an intact septum, of which at least 12 are LAAC, over a 2-year period.

The patient is enrolled in, and the MDT and hospital must participate in, a prospective, national, audited registry that: 1) consecutively enrolls LAAC patients, and, 2) tracks the following annual outcomes for each patient for a period of at least 4 years from the time of the LAAC:

- Operator-specific complications
- Device-specific complications including device thrombosis
- Stroke, adjudicated, by type

- Transient Ischemic Attack (TIA)
- Systemic embolism
- Death
- Major bleeding, by site and severity

CPT Codes

33267 Exclusion of left atrial appendage, open, any method
33268 Exclusion of left atrial appendage, open, performed at the time of other sternotomy or thoracotomy procedure(s), any method
33269 Exclusion of left atrial appendage, thoracoscopic, any method

Limitations

SummaCare considers cardiac devices for occlusion of the left atrial appendage experimental and investigational for all other indications.

Coverage Decisions

Coverage decisions made per CMS Guidelines, Hayes Research and industry standards research

Plans Covered By This Policy

Commercial and Medicare
Self-funded Commercial groups refer to plan document for coverage

Sources Reviewed

Gage BF, Waterman AD, Shannon W, et al. Validation of clinical classification schemes for predicting stroke: results from the National Registry of Atrial Fibrillation. JAMA 2001; 285:2864.

Lip GYH, Nieuwlaat R, Pisters R, et al. 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; 137:263.

Fuster, V. M.-C., & Ryden, L. E. (2006). ACC/AHA/ESC 2006 Guidelines for the Management of Patients with Atrial Fibrillation. Circulation, e257-e354.

Krzysztof B, G. S. (2016). Left atrial appendage ligation with the next generation LARIAT suture deliver device: Early Clinical Experience. International Journal of Cardiology, 244-247. Meschia, J.

B.-A., ba, & al., a. B. (2014). Guidelines for the prevention of stroke: a statement for healthcare professionals from the American Heart Association/American Stroke Association. Stroke, 37543832.

Reddy VY, G. D. (2016). Post-FDA Approval, Initial US Clinical Experience with Watchman Left Atrial Appendage Closure for Stroke Prevention in Atrial Fibrillation. Journal of the American College of Cardiology.

Sergio B, S. G. (2017). Left atrial appendage closure using AMPLATZER devices: A large, multicenter, Italian registry. International Journal of Cardiology, 103-107

Percutaneous Left Atrial Appendage Closure (LAAC). CMS https://www.cms.gov/medicare-coverage-database/view/ncd.aspx?NCDId=367