Left Atrial Appendage Closure Devices

Origination: 04/24/14	**Revised:** 05/03/23	**Annual Review:** 10/13/22

Purpose:

The Medical Technology Assessment Committee will review published scientific literature and information from appropriate government regulatory bodies (when available) related to Left *Atrial Appendage Closure Devices* in order to determine inclusion in the benefit plan.

Recommendation:

A recommendation was made by the MTAC following discussion by committee members based on current literature:

Left Atrial Appendage Closure (LAAC) devices are covered when the device has received Food and Drug Administration (FDA) Premarket Approval for that device's FDA-approved indication and meet all 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. LAAC is only covered as a second line therapy to oral anticoagulants.
- 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), electrophysiologst(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.

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Experimental and Investigational

Cardiac devices for occlusion of the left atrial appendage are considered experimental and investigational for all other indications not listed above.

Use of any LAAC device other than the Amplatzer Amulet Left Atrial Appendage Occluder, and the Watchman device (e.g., Amplatzer Cardiac Plug, and Lariat Suture Delivery Device) is considered experimental and investigational.

References:

1. Centers for Medicare & Medicaid Services (CMS). Decision Merno for Percutaneous Left Atrial Appendage (LAA) Closure Therapy (CAG-00445N). Baltimore, MD: CMS; February 8, 2016 and NCD 100.3 Percutaneous Left Atrial Appendage Closure.
2. Abbott Laboratories. Abbott's Amplatzer™" Amulet™ device approved by FDA to treat people with atrial fibrillation at risk of stroke. Press Release. Abbott Park, IL: Abbott, August 16, 2021.
3. Aminian A, Lalmand J, Tzikas A, et al. Embolization of left atrial appendage closure devices: A systematic review of cases reported with the watchman device and the amplatzer cardiac plug. Catheter Cardiovasc Interv. 2015;86(1):128- 135.
4. Anderson JL, Halperin JL, Albert NM, et al. Management of patients with atrial fibrillation (Compilation of 2006 ACCF/AHA/ESC and 2011 ACC/AHA/HRS Recommendations). A Report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines. Circulation. 2013
5. Agnuma K Yamasaki H, Nakamura M, et al. Percutaneous WATCHMAN left atrial appendage cosure for Japanese patients with nonvalvular atrial fibrillation at increased risk of thromboembolism - First results from the SALUTE trial. Circ J. 2018

Disclaimer Information:

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