Left Atrial Appendage Closure Devices

Origination: 04/19/23	**Revised:** 12/18/23	**Annual Review:** 12/19/23
Line of Business: Commercial Only ☐ QHP/Exchange Only ☐ Medicare Only ☐ Commercial & QHP/Exchange ☒ Commercial, QHP/Exchange, & Medicare ☐		

Purpose:

The Medical Technology Assessment Committee reviewed 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.

To provide guidelines for Left Atrial Appendage Closure Devices for Population Health and Provider Alliances associates for reference when making benefit determinations.

Coverage Guidelines:

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), 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.

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Exclusion Criteria

- LAAC devices that are not covered as are considered to be investigational includes but is not restricted to: The Amplatzer cardiac plug; the Amulet; the AtriClip device; the Lariat snare device; the PLAATO device; the Watchman device; and procedures such as epicardial clipping of the left atrial appendage; and left atrial appendectomy.

References:

1. National Coverage Determination for Percutaneous Left Atrial Appendage Closure (LAAC) NCD 20.34. Effective Date 2/8/16. Revised Jan. 2023

2. Coverage with Evidence Development-Percutaneous Left Atrial Appendage Closure. CMS Approval Date 8/17/16.

3. American College of Cardiology -Tools and Practice Support-Atrial Fibrillation Toolkit.

Disclaimer Information:

Coverage Issues Guidelines and Medical Technology Assessment Recommendations are developed to determine coverage for AvMed's benefits and are published to provide a better understanding of the basis upon which coverage decisions are made. AvMed makes coverage decisions using these guidelines, along with the Member's benefit document. The use of this guideline is neither a guarantee of payment nor a final prediction of how specific claim(s) will be adjudicated.

Coverage Issues Guidelines and Medical Technology Assessment Recommendations are developed for selected therapeutic or diagnostic services found to be safe, but proven effective in a limited, defined population of patients or clinical circumstances. They include concise clinical coverage criteria based on current literature review, consultation with practicing physicians in the AvMed service area who are medical experts in the particular field, FDA and other government agency policies, and standards adopted by national accreditation organizations.

Treating providers are solely responsible for the medical advice and treatment of Members. This guideline may be updated and therefore is subject to change.