

Left Atrial Appendage Closure (LAAC) “Watchman”

National Coverage Determination (NCD) Background

- March 13, 2015: FDA approved the WATCHMAN™ LAA Closure Technology.
- May 21, 2015: CMS accepted formal request from Boston Scientific for Percutaneous LAAC therapy.
- February 8, 2016: [Decision Memo](#) for Percutaneous Left Atrial Appendage (LAA) Closure Therapy (CAG-00445N) published.
- February 8, 2016: Effective Date for National Coverage Determination (NCD) for Percutaneous Left Atrial Appendage Closure (LAAC) ([20.34](#)).

NCD 20.34 Indications and Limitations of Coverage

CMS covers this procedure for **non-valvular atrial fibrillation (NVAF)** through Coverage with Evidence Development (CED) with the following conditions:

Device must have received FDA Premarket Approval (PMA) for that device’s FDA-approved indication and meet all of the conditions specified below:

The **patient must have:**

- CHADS2 score ≥ 2 (Congestive Heart Failure, HTN, Age >75 , Diabetes, Stroke/TIA/Thromboembolism) **OR** CHA2DS2 – VASc score ≥ 3 (Congestive Heart Failure, HTN, Age ≥ 65 , Diabetes, Stroke/TIA/Thromboembolism, Vascular disease, sex category)
- Formal Shared Decision Making (SDM) 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 SDM interaction must be documented in the medical record**.
- A suitability for short-term warfarin (Coumadin) **but deemed unable to take long-term 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.

Note, CMS made the following recommendation regarding the MDT in the Final Decision memo: *We recommend the patient care team include pre-operative and post-operative team members, and include the addition of two independent non-interventionalists that include two of the following: the patient’s primary care provider, who has the most comprehensive knowledge of the patient; a non-interventional cardiologist; or a neurologist who has experience caring for stroke patients. We believe a MDT provides continuity of care that is key to successful health outcomes.*

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

For devices and indications that are not approved by FDA, patients must be enrolled in a qualifying FDA-approved Randomized Controlled Trial (RCT). The clinical study must address pre-specified research questions, adhere to standards of scientific integrity, and be approved by CMS. The process for submitting a clinical research study to Medicare is outlined in the NCD.

The LAAC Registry and Clinical Study Approvals are posted on the CMS CED website at:

<https://www.cms.gov/Medicare/Coverage/Coverage-with-Evidence-Development/LAAC.html>

NCD 20.34 Nationally Non-Covered Indications LAAC is non-covered for the treatment of NVAF when not furnished under CED according to the above-noted criteria.

Hospital Inpatient Only Procedure

The LAAC procedure is on the Medicare “Inpatient-Only” Procedure (IPO) List and is not an approved procedure in the outpatient hospital setting for Medicare beneficiaries. The Medicare IPO list defines services that support an inpatient admission and Part A payment as appropriate, regardless of the expected length of stay. CMS has directed Medicare Administrative Contractors (MACs) to approve these cases so long as other requirements (i.e., NCD indications and limitations of coverage) are met.

ICD-10 Procedure and Diagnosis Codes, Claims Requirements and MS-DRG Assignment for LAAC Procedure

This procedure is covered under Coverage with Evidence Development (CED). This means the claims must include a secondary diagnosis code, condition code, and value code related to the clinical trial/registry.

- ICD-10 Procedure Code: 02L73DK (Occlusion of Left Atrial Appendage with Intraluminal Device, Percutaneous Approach)
- Covered Primary ICD-10 Diagnosis Code (one of the following):
 - I48.0 – Paroxysmal atrial fibrillation
 - I48.1 – Persistent atrial fibrillation
 - I48.2 – Chronic atrial fibrillation, or
 - I48.9 – Unspecified atrial fibrillation

- Secondary Diagnosis code – Z00.6 (Encounter for examination for normal comparison and control in research program)
- Condition Code 30 – Qualified Clinical Trial
- Value Code D4 and corresponding 8-digit clinical trial number (Clinical trial and/or registry numbers can be found on Medicare’s [CED](#) website.)
- MS-DRGs Assignment:
 - 273: Percutaneous Intracardiac Procedures with MCC, or
 - 274: Percutaneous Intracardiac Procedures without MCC

How to Avoid Denials for Inpatient Percutaneous Left Atrial Appendage Closure (LAAC) Services

In August 2019, Palmetto GBA, the Medicare Administrative Contractor (MAC) for Jurisdiction J (AL, GA, and TN) posted an article on their website regarding [CERT denials of inpatient claims for LAAC](#) procedures. The following two key reasons for denials were included in the article:

- Missing documentation to support the need for the LAAC procedure. Reminder, CMS covers this procedure for patients with non-valvular atrial fibrillation.
- The submitted medical records were missing evidence of a formal shared decision making interaction with an independent non-interventional physician using an evidence-based decision tool on oral anticoagulation in patients with non-ventricular atrial fibrillation prior to LAAC.

Shared Decision Making for LAAC Procedure

Resources to assist in the SDM process with your patients:

- CardioSmart – American College of Cardiology’s CardioSmart website at <https://www.cardiosmart.org/AFibDecisionAids>
- Boston Scientific Booklet: *Shared Decision Making: An Evidence-Based Cornerstone of LAAC Therapy* at https://www.watchman.com/content/dam/watchman/downloads/download-center/WATCHMAN_Shared_Decision_Making_Brochure.pdf
- WATCHMAN.com website for information about the Procedure, Clinical Evidence, Patient Selections and Referrals, Coverage and Cost, and Implant Centers at: <https://www.watchman.com/en-us-hcp/implant-center-locator.html>

Disclaimer: This material was compiled to share information. MMP is not offering legal advice. This material was current at the time it was compiled. Every reasonable effort has been taken to ensure the information is accurate and useful.

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