



Medicare Medical Coverage Policy

Percutaneous Left Atrial Appendage Closure (LAAC)

Origination: August 23, 2017

Review Date: August 18, 2021

Next Review: August, 2023

******This policy applies to all Blue Medicare HMO, Blue Medicare PPO, Blue Medicare Rx members, and members of any third-party Medicare plans supported by Blue Cross NC through administrative or operational services. ******

DESCRIPTION OF PROCEDURE

Percutaneous Left Atrial Appendage Closure- 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. 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 AF.

DEFINITIONS:

Coverage with Evidence Development (CED): CMS at times, issues a coverage decision with data collection being a part of the condition for coverage. The CED concept considers the item or service to be reasonable and necessary only while evidence is being developed regarding a member's health outcomes in a clinical trial. CMS maintains a registry of facilities that have agreed to the clinical indications specified in the coverage decision. CMS lists clinical trials with CED at <https://www.cms.gov/Medicare/Coverage/Coverage-with-Evidence-Development/LAAC.html>

POLICY STATEMENT

Coverage will be provided for LAAC under CED based on meeting CMS conditions as outlined in the National Coverage Determination.

BENEFIT APPLICATION

Please refer to the member's individual Evidence of Coverage (E.O.C.) for benefit determination. Coverage will be approved according to the E.O.C. limitations, if the criteria are met.

Coverage decisions will be made in accordance with:

- The Centers for Medicare & Medicaid Services (CMS) National Coverage Determinations (NCDs);

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- General coverage guidelines included in Original Medicare manuals unless superseded by operational policy letters or regulations; and
- Written coverage decisions of local Medicare carriers and intermediaries with jurisdiction for claims in the geographic area in which services are covered.

Benefit payments are subject to contractual obligations of the Plan. If there is a conflict between the general policy guidelines contained in the Medical Coverage Policy Manual and the terms of the member's particular Evidence of Coverage (E.O.C.), the E.O.C. always governs the determination of benefits.

INDICATIONS FOR COVERAGE

1. Member has Non-Valvular Atrial Fibrillation (NVAF); **AND**
2. The device is FDA approved for percutaneous LAA closure; **AND**
3. The indication for coverage is that the member be a CHADS2 score ≥ 2 (CHF, HTN, Age >75 , Diabetes, Stroke/TIA/thromboembolism) or CHA2DS2-VASc score ≥ 3 (CHF, HTN, Age ≥ 65 , Diabetes, Stroke/TIA/thromboembolism, Vascular disease, Sex category) **AND**
4. There must be documented in the medical record a formal shared decision making interaction with a non-interventional physician (ex. Cardiologist, PCP), using the CHADS2 or CHA2DS2 calculator in patients with NVAF prior to LAAC.
5. The member must be suitable 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.
6. The Hospital must participate in LAAO registry at the provided link:
<https://cvquality.acc.org/NCDR-Home/participant-directory>

WHEN COVERAGE WILL NOT BE APPROVED

LAAC is non-covered for the treatment of NVAF when not furnished under CED according to the criteria outlined in the NCD.

BILLING/ CODING/PHYSICIAN DOCUMENTATION INFORMATION

This policy may apply to the following codes. Inclusion of a code in the section does not guarantee reimbursement.

Applicable codes: 33340

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The Plan may request medical records for determination of medical necessity. When medical records are requested, letters of support and/or explanation are often useful, but are not sufficient documentation unless all specific information needed to make a medical necessity determination is included.

SPECIAL NOTES

When the above criteria are met, staff will complete an appropriate level of care authorization.

CHADS2 and CHA2DS2-VASc scores are determined by utilizing a calculator which takes into consideration pieces of a member's clinical condition. Here is a link where you can access an example of one of these for reference purposes. This example will help identify key pieces of information that should be part of the shared decision making consult and documented in the medical record. <https://www.mdcalc.com/chads2-score-atrial-fibrillation-stroke-risk>.

References: (Arial 10)

1. National Coverage Determination for Percutaneous Left Atrial Appendage Closure (LAAC) 20.34. Effective Date 2/8/16. Accessed at www.cms.gov on 7/22/21.
2. Coverage with Evidence Development-Percutaneous Left Atrial Appendage Closure. CMS Approval Date 8/17/16. Accessed at <https://www.cms.gov/Medicare/Coverage/Coverage-with-Evidence-Development/LAAC.html> on 7/22/21.
3. American College of Cardiology -Tools and Practice Support-Atrial Fibrillation Toolkit; <http://www.acc.org/tools-and-practice-support/clinical-toolkits/atrial-fibrillation-afib?w.nav=MN> Accessed on 7/12/17.

Policy Implementation/Update Information:

Revision Date:

New Policy: August 23, 2017

August 21, 2019: Annual Review; No CMS Updates. Minor Revisions Only.

August 18, 2021; Annual Review; No CMS Updates. Minor Revisions Only.

March 16, 2022; Staff Clarification; Updated Special Notes; "complete an appropriate level of care authorization."

Approval Dates:

Medical Coverage Policy Committee: March 16, 2022

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