

Percutaneous Left Atrial Appendage Closure (LAAC) (NCD 20.34)

Guideline Number: MPG361.06

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[Terms and Conditions](#)

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Related Medicare Advantage Policy Guidelines

- [Category III CPT Codes](#)
- [Routine Costs in Clinical Trials \(NCD 310.1\)](#)

Related Medicare Advantage Coverage Summaries

- [Experimental Procedures and Items, Investigational Devices and Clinical Trials](#)
- [Transcatheter Heart Valve Procedures](#)

Policy Summary

[See Purpose](#)

Overview

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. 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.

Guidelines

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:

- A. 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 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.
 - 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.

- 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
 - Systemic embolism
 - Device-specific complications including device thrombosis
 - Transient Ischemic Attack (TIA)
 - Stroke, adjudicated, by type
 - Death
 - Major bleeding, by site and severity
- The registry must be designed to permit identification and analysis of patient, practitioner, and facility level factors that predict patient risk for these outcomes. The registry must collect all data necessary to conduct analyses adjusted for relevant confounders, and have a written executable analysis plan in place to address the following questions:
 - How do the outcomes listed above compare to outcomes in the pivotal clinical trials in the short term (≤ 12 months) and in the long term (≥ 4 years)?
 - What is the long term (≥ 4 year) durability of the device?
 - What are the short term (≤ 12 months) and the long term (≥ 4 years) device-specific complications including device thromboses?
- To appropriately address some of these questions, Medicare claims or other outside data may be necessary.
- Registries must be reviewed and approved by CMS. Potential registry sponsors must submit all registry documentation to CMS for approval, including the written executable analysis plan and auditing plan. CMS will review the qualifications of candidate registries to ensure that the approved registry follows standard data collection practices, and collects data necessary to evaluate the patient outcomes specified above. The registry's national clinical trial number must be recorded on the claim.
- Consistent with section 1142 of the Social Security Act (the Act), the Agency for Healthcare Research and Quality (AHRQ) supports clinical research studies that CMS determines address the above-listed research questions and the a-m criteria listed in Section c. of this decision.
- All approved registries will be posted on the CED website located at: <https://www.cms.gov/Medicare/Coverage/Coverage-with-Evidence-Development/index.html>

B. LAAC is covered for NVAf patients not included in Section A of this decision when performed within an FDA-approved randomized controlled trial (RCT) if such trials meet the criteria established below:

- As a fully-described written part of its protocol, the RCT must critically answer, in comparison to optimal medical therapy, the following questions:
 - As a primary endpoint, what is the true incidence of ischemic stroke and systemic embolism?
 - As a secondary endpoint, what is cardiovascular mortality and all-cause mortality?
- FDA-approved RCTs must be reviewed and approved by CMS. Consistent with section 1142 of the Act, AHRQ supports clinical research studies that CMS determines address the above-listed research questions and the a-m criteria listed in Section c. of this decision.
- The principal investigator must submit the complete study protocol, identify the relevant CMS research question(s) that will be addressed, and cite the location of the detailed analysis plan for those questions in the protocol, plus provide a statement addressing how the study satisfies each of the standards of scientific integrity a. through m. listed in section c. of this decision, as well as the investigator's contact information, to the address below:

Director, Coverage and Analysis Group
 Re: LAAC CED
 Centers for Medicare & Medicaid Services
 7500 Security Blvd., Mail Stop S3-02-01

- C. All clinical studies, RCTs and registries submitted for review must adhere to the following standards of scientific integrity and relevance to the Medicare population:
- The principal purpose of the study is to test whether the item or service meaningfully improves health outcomes of affected beneficiaries who are represented by the enrolled subjects.
 - The rationale for the study is well supported by available scientific and medical evidence.
 - The study results are not anticipated to unjustifiably duplicate existing knowledge.
 - The study design is methodologically appropriate and the anticipated number of enrolled subjects is sufficient to answer the research question(s) being asked in the National Coverage Determination.
 - The study is sponsored by an organization or individual capable of completing it successfully.
 - The research study is in compliance with all applicable Federal regulations concerning the protection of human subjects found in the Code of Federal Regulations (CFR) at 45 CFR Part 46. If a study is regulated by the FDA, it is also in compliance with 21 CFR Parts 50 and 56. In addition, to further enhance the protection of human subjects in studies conducted under CED, the study must provide and obtain meaningful informed consent from patients regarding the risks associated with the study items and/or services, and the use and eventual disposition of the collected data.
 - All aspects of the study are conducted according to appropriate standards of scientific integrity.
 - The study has a written protocol that clearly demonstrates adherence to the standards listed here as Medicare requirements.
 - The study is not designed to exclusively test toxicity or disease pathophysiology in healthy individuals. Such studies may meet this requirement only if the disease or condition being studied is life threatening as defined in 21 CFR §312.81(a) and the patient has no other viable treatment options.
 - The clinical research studies and registries are registered on the <https://clinicaltrials.gov/> website by the principal sponsor/investigator prior to the enrollment of the first study subject. Registries are also registered in the AHRQ Registry of Patient Registries (RoPR).
 - The research study protocol specifies the method and timing of public release of all prespecified outcomes to be measured including release of outcomes if outcomes are negative or study is terminated early. The results must be made public within 12 months of the study's primary completion date, which is the date the final subject had final data collection for the primary endpoint, even if the trial does not achieve its primary aim. The results must include number started/completed, summary results for primary and secondary outcome measures, statistical analyses, and adverse events. Final results must be reported in a publicly accessible manner; either in a peer-reviewed scientific journal (in print or on-line), in an on-line publicly accessible registry dedicated to the dissemination of clinical trial information such as ClinicalTrials.gov, or in journals willing to publish in abbreviated format (e.g., for studies with negative or incomplete results).
 - The study protocol must explicitly discuss beneficiary subpopulations affected by the item or service under investigation, particularly traditionally underrepresented groups in clinical studies, how the inclusion and exclusion criteria effect enrollment of these populations, and a plan for the retention and reporting of said populations in the trial. If the inclusion and exclusion criteria are expected to have a negative effect on the recruitment or retention of underrepresented populations, the protocol must discuss why these criteria are necessary.
 - The study protocol explicitly discusses how the results are or are not expected to be generalizable to affected beneficiary subpopulations. Separate discussions in the protocol may be necessary for populations eligible for Medicare due to age, disability, or Medicaid eligibility.

Nationally Non-Covered Indications

LAAC is non-covered for the treatment of NVAf when not furnished under CED according to the above-noted criteria.

Applicable Codes

The following list(s) of procedure and/or diagnosis codes is provided for reference purposes only and may not be all inclusive. Listing of a code in this guideline does not imply that the service described by the code is a covered or non-covered health service. Benefit coverage for health services is determined by the member specific benefit plan document and applicable laws that may require coverage for a specific service. The inclusion of a code does not imply any right to reimbursement or guarantee claim payment. Other Policies and Guidelines may apply.

CPT Code	Description
33340	Percutaneous transcatheter closure of the left atrial appendage with implant, including fluoroscopy, transseptal puncture, catheter placement(s), left atrial angiography, left atrial appendage angiography, radiological supervision and interpretation

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Modifier	Description
Q0	Investigational clinical service provided in a clinical research study that is in an approved clinical research study

Condition Code	Description
30	Qualifying Clinical Trial

Place of Service Code	Description
21	Inpatient Hospital

ICD Procedure Code	Description
02L73DK	Occlusion of left atrial appendage with intraluminal device, percutaneous approach

References

CMS National Coverage Determinations (NCDs)

[NCD 20.34 Percutaneous Left Atrial Appendage Closure \(LAAC\)](#)

CMS Benefit Policy Manual

[Chapter 14 Medical Devices](#)

CMS Claims Processing Manual

[Chapter 32; § 68 Investigational Device Exemption \(IDE\) Studies, § 69 – 69.11 Qualifying Clinical Trials](#)

CMS Transmittal(s)

[Transmittal 192, Change Request 9638, Dated 05/06/2016 \(Percutaneous Left Atrial Appendage Closure \(LAAC\)\)](#)

[Transmittal 1798, Change Request 9982, Dated 02/17/2017 \(ICD-10 Coding Revisions to National Coverage Determinations \(NCDs\)\)](#)

[Transmittal 2382, Change Request 11491, Dated 11/01/2019 \(International Classification of Diseases, 10th Revision \(ICD-10\) and Other Coding Revisions to National Coverage Determination \(NCDs\) – April 2020 Update\)](#)

[Transmittal 2427, Change Request 11491, Dated 02/04/2020 \(International Classification of Diseases, 10th Revision \(ICD-10\) and Other Coding Revisions to National Coverage Determination \(NCDs\) – April 2020 Update\)](#)

[Transmittal 3515, Change Request 9638, Dated 05/06/2016 \(Percutaneous Left Atrial Appendage Closure \(LAAC\)\)](#)

MLN Matters

[Article MM5790, Use of an 8-Digit Registry Number on Clinical Trial Claims](#)

[Article MM8401, Revised June 9, 2014: Mandatory Reporting of an 8-Digit Clinical Trial Number on Claims](#)

[Article MM9638, Percutaneous Left Atrial Appendage Closure \(LAAC\)](#)

[Article MM11491 Revised, International Classification of Diseases, 10th Revision \(ICD-10\) and Other Coding Revisions to National Coverage Determination \(NCDs\) – April 2020 Update](#)

[Article SE1344, Further Information on Mandatory Reporting of an 8-Digit Clinical Trial Number on Claims](#)

UnitedHealthcare Commercial Policy

[Omnibus Codes](#)

Other(s)

[CMS Mandatory Reporting of National Clinical Trial \(NCT\) Identifier](#)

[Decision Memo for Percutaneous Left Atrial Appendage \(LAA\) Closure Therapy \(CAG-00445N\), CMS Website](#)

Guideline History/Revision Information

Revisions to this summary document do not in any way modify the requirement that services be provided and documented in accordance with the Medicare guidelines in effect on the date of service in question.

Date	Summary of Changes
04/01/2021	Template Update <ul style="list-style-type: none">Reformatted policy; transferred content to new template
06/10/2020	Questions and Answers <ul style="list-style-type: none">Removed Q&A addressing the issue date of the National Coverage Determination (NCD) for <i>Percutaneous Left Atrial Appendage Closure (LAAC) (20.34)</i> Supporting Information <ul style="list-style-type: none">Archived previous policy version MPG361.05

Purpose

The Medicare Advantage Policy Guideline documents are generally used to support UnitedHealthcare Medicare Advantage claims processing activities and facilitate providers' submission of accurate claims for the specified services. The document can be used as a guide to help determine applicable:

- Medicare coding or billing requirements, and/or
- Medical necessity coverage guidelines; including documentation requirements.

UnitedHealthcare follows Medicare guidelines such as NCDs, LCDs, LCAs, and other Medicare manuals for the purposes of determining coverage. It is expected providers retain or have access to appropriate documentation when requested to support coverage. Please utilize the links in the [References](#) section below to view the Medicare source materials used to develop this resource document. This document is not a replacement for the Medicare source materials that outline Medicare coverage requirements. Where there is a conflict between this document and Medicare source materials, the Medicare source materials will apply.

Terms and Conditions

The Medicare Advantage Policy Guidelines are applicable to UnitedHealthcare Medicare Advantage Plans offered by UnitedHealthcare and its affiliates.

These Policy Guidelines are provided for informational purposes, and do not constitute medical advice. Treating physicians and healthcare providers are solely responsible for determining what care to provide to their patients. Members should always consult their physician before making any decisions about medical care.

Benefit coverage for health services is determined by the member specific benefit plan document* and applicable laws that may require coverage for a specific service. The member specific benefit plan document identifies which services are covered, which are excluded, and which are subject to limitations. In the event of a conflict, the member specific benefit plan document supersedes the Medicare Advantage Policy Guidelines.

Medicare Advantage Policy Guidelines are developed as needed, are regularly reviewed and updated, and are subject to change. They represent a portion of the resources used to support UnitedHealthcare coverage decision making.

UnitedHealthcare may modify these Policy Guidelines at any time by publishing a new version of the policy on this website. Medicare source materials used to develop these guidelines include, but are not limited to, CMS National Coverage Determinations (NCDs), Local Coverage Determinations (LCDs), Medicare Benefit Policy Manual, Medicare Claims Processing Manual, Medicare Program Integrity Manual, Medicare Managed Care Manual, etc. The information presented in the Medicare Advantage Policy Guidelines is believed to be accurate and current as of the date of publication and is provided on an "AS IS" basis. Where there is a conflict between this document and Medicare source materials, the Medicare source materials will apply.

You are responsible for submission of accurate claims. Medicare Advantage Policy Guidelines are intended to ensure that coverage decisions are made accurately based on the code or codes that correctly describe the health care services provided. UnitedHealthcare Medicare Advantage Policy Guidelines use Current Procedural Terminology (CPT®), Centers for Medicare and Medicaid Services (CMS), or other coding guidelines. References to CPT® or other sources are for definitional purposes only and do not imply any right to reimbursement or guarantee claims payment.

Medicare Advantage Policy Guidelines are the property of UnitedHealthcare. Unauthorized copying, use, and distribution of this information are strictly prohibited.

*For more information on a specific member's benefit coverage, please call the customer service number on the back of the member ID card or refer to the [Administrative Guide](#).