

<b>CMS Manual System</b>	<b>Department of Health &amp; Human Services (DHHS)</b>
<b>Pub 100-03 Medicare National Coverage Determinations</b>	<b>Centers for Medicare &amp; Medicaid Services (CMS)</b>
<b>Transmittal 192</b>	<b>Date: May 6 2016</b>
	<b>Change Request 9638</b>

**SUBJECT: Percutaneous Left Atrial Appendage Closure (LAAC)**

**I. SUMMARY OF CHANGES:** The purpose of this Change Request (CR) is to inform contractors that the Centers for Medicare & Medicaid Services (CMS) issued a National Coverage Determination (NCD) covering Percutaneous Left Atrial Appendage Closure (LAAC) through Coverage with Evidence Development (CED) when LAAC is furnished in patients with Non-Valvular Atrial Fibrillation (NVAf) and according to an FDA approved indication for percutaneous LAAC with an FDA-approved device.

This revision to the Medicare National Coverage Determinations Manual is a national coverage determination (NCD). NCDs are binding on all carriers, fiscal intermediaries, contractors with the Federal government that review and/or adjudicate claims, determinations, and/or decisions, quality improvement organizations, qualified independent contractors, the Medicare appeals council, and administrative law judges (ALJs) (see 42 CFR section 405.1060(a)(4) (2005)). An NCD that expands coverage is also binding on a Medicare advantage organization. In addition, an ALJ may not review an NCD. (See section 1869(f)(1)(A)(i) of the Social Security Act.)

**EFFECTIVE DATE: February 8, 2016**

*\*Unless otherwise specified, the effective date is the date of service.*

**IMPLEMENTATION DATE: October 3, 2016**

*Disclaimer for manual changes only: The revision date and transmittal number apply only to red italicized material. Any other material was previously published and remains unchanged. However, if this revision contains a table of contents, you will receive the new/revised information only, and not the entire table of contents.*

**II. CHANGES IN MANUAL INSTRUCTIONS:** (N/A if manual is not updated)

R=REVISED, N=NEW, D=DELETED-*Only One Per Row.*

<b>R/N/D</b>	<b>CHAPTER / SECTION / SUBSECTION / TITLE</b>
N	1/20.34/Percutaneous Left Atrial Appendage Closure (LAAC)

**III. FUNDING:**

**For Medicare Administrative Contractors (MACs):**

The Medicare Administrative Contractor is hereby advised that this constitutes technical direction as defined in your contract. CMS does not construe this as a change to the MAC Statement of Work. The contractor is not obligated to incur costs in excess of the amounts allotted in your contract unless and until specifically authorized by the Contracting Officer. If the contractor considers anything provided, as described above, to be outside the current scope of work, the contractor shall withhold performance on the part(s) in question and immediately notify the Contracting Officer, in writing or by e-mail, and request formal directions regarding continued performance requirements.

**IV. ATTACHMENTS:**

**Business Requirements  
Manual Instruction**

# Attachment - Business Requirements

Pub. 100-03	Transmittal: 192	Date: May 6, 2016	Change Request: 9638
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**SUBJECT: Percutaneous Left Atrial Appendage Closure (LAAC)**

**EFFECTIVE DATE: February 8, 2016**

*\*Unless otherwise specified, the effective date is the date of service.*

**IMPLEMENTATION DATE: October 3, 2016**

## I. GENERAL INFORMATION

**A. Background:** Left atrial appendage closure (LAAC) is a strategy to reduce the risk of stroke by closing the left atrial appendage (LAA) in patients with non-valvular atrial fibrillation (NVAF). Patients with NVAF, an abnormally rapid, irregular heartbeat, are at an increased risk of stroke. Some evidence suggests that many of the strokes attributed to NVAF originate from the LAA. The LAA is a tubular structure that opens into the left atrium of the heart. LAAC with a percutaneously implanted device could be used in patients with NVAF to reduce cardioembolic stroke risk as a potential alternative to oral anticoagulation.

**B. Policy:** On February 8, 2016, the Centers for Medicare & Medicaid Services (CMS) issued a National Coverage Determination (NCD) covering percutaneous LAAC through Coverage with Evidence Development (CED) when LAAC is furnished in patients with NVAF and according to an FDA approved indication for percutaneous LAAC with an FDA-approved device. Coverage requires that patients must have:

- A CHADS2 score  $\geq 2$  (Congestive heart failure, Hypertension, Age  $>75$ , Diabetes, Stroke/transient ischemia attack/thromboembolism) or CHA2DS2-VASc score  $\geq 3$  (Congestive heart failure, Hypertension, Age  $\geq 65$ , 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 following the conclusion of shared decision making, as LAAC is only covered as a second line therapy to oral anticoagulants..

The NCD lists the criteria for the physician and facility criteria and includes a requirement for a multidisciplinary team to be engaged in patient care.

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. Approved studies will be posted on the CMS website at <https://www.cms.gov/Medicare/Coverage/Coverage-with-Evidence-Development/LAAC.html>. The process for submitting a clinical research study to Medicare is outlined in the NCD.

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

## II. BUSINESS REQUIREMENTS TABLE

"Shall" denotes a mandatory requirement, and "should" denotes an optional requirement.

Number	Requirement	Responsibility									
		A/B MAC			D M E M A C	Shared- System Maintainers				Other	
		A	B	H H H		F I S S	M C S	V M S	C W F		
9638 - 03.1	<p>Effective February 8, 2016, contractors shall cover percutaneous LAAC through Coverage with Evidence Development (CED) when LAAC is furnished in patients with NVAF and according to an FDA approved indication for percutaneous LAAC with an FDA-approved device.</p> <p>Please refer to NCD Manual Section 20.34 for policy.</p>	X	X								

## III. PROVIDER EDUCATION TABLE

Number	Requirement	Responsibility					
		A/B MAC			D M E M A C	C E D I	
		A	B	H H H			
9638 - 03.2	<p>MLN Article: A provider education article related to this instruction will be available at <a href="http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/">http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/</a> shortly after the CR is released. You will receive notification of the article release via the established "MLN Matters" listserv. Contractors shall post this article, or a direct link to this article, on their Web sites and include information about it in a listserv message within 5 business days after receipt of the notification from CMS announcing the availability of the article. In addition, the provider education article shall be included in the contractor's next regularly scheduled bulletin. Contractors are free to supplement MLN Matters articles with localized information that would benefit their provider community in billing and administering the Medicare program correctly.</p>	X	X				

#### IV. SUPPORTING INFORMATION

**Section A: Recommendations and supporting information associated with listed requirements: N/A**

*"Should" denotes a recommendation.*

X-Ref Requirement Number	Recommendations or other supporting information:
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**Section B: All other recommendations and supporting information: N/A**

#### V. CONTACTS

**Pre-Implementation Contact(s):** Patricia Brocato-Simons, 410-786-0261 or Patricia.BrocatoSimons@cms.hhs.gov (Coverage and Analysis Group) , Felicia Rowe, 410-786-5655 or Felicia.Rowe@cms.hhs.gov (Institutional Claims) , Kimberly Long, 410-786-5702 or Kimberly.Long@cms.hhs.gov (Coverage and Analysis Group) , Wanda Belle, 410-786-7491 or Wanda.Belle@cms.hhs.gov (Coverage and Analysis Group) , Mark Baldwin, 410-786-8139 or Mark.Baldwin@cms.hhs.gov (Professional Claims)

**Post-Implementation Contact(s):** Contact your Contracting Officer's Representative (COR).

#### VI. FUNDING

**Section A: For Medicare Administrative Contractors (MACs):**

The Medicare Administrative Contractor is hereby advised that this constitutes technical direction as defined in your contract. CMS does not construe this as a change to the MAC Statement of Work. The contractor is not obligated to incur costs in excess of the amounts allotted in your contract unless and until specifically authorized by the Contracting Officer. If the contractor considers anything provided, as described above, to be outside the current scope of work, the contractor shall withhold performance on the part(s) in question and immediately notify the Contracting Officer, in writing or by e-mail, and request formal directions regarding continued performance requirements.

**ATTACHMENTS: 0**

## **20.34 Percutaneous Left Atrial Appendage Closure (LAAC)** **(Rev.192, Issued: 05-06-16, Effective: 02-08-16, Implementation: 10-03-16)**

### **A. General**

*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. 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.*

### **B. 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:*

- o A CHADS2 score  $\geq 2$  (Congestive heart failure, Hypertension, Age  $>75$ , Diabetes, Stroke/transient ischemia attack/thromboembolism) or CHA2DS2-VASc score  $\geq 3$  (Congestive heart failure, Hypertension, Age  $\geq 65$ , Diabetes, Stroke/transient ischemia attack/thromboembolism, Vascular disease, Sex category)*
- o 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.*
- o 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.*

*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  $\geq 25$  interventional cardiac procedures that involve transeptal puncture through an intact septum; and,*
- Continues to perform  $\geq 25$  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

*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 ( $\leq 12$  months) and in the long term ( $\geq 4$  years)?*
- *What is the long term ( $\geq 4$  year) durability of the device?*
- *What are the short term ( $\leq 12$  months) and the long term ( $\geq 4$  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*

- 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:*
- a. *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.*
  - b. *The rationale for the study is well supported by available scientific and medical evidence.*
  - c. *The study results are not anticipated to unjustifiably duplicate existing knowledge.*
  - d. *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.*
  - e. *The study is sponsored by an organization or individual capable of completing it successfully.*
  - f. *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.*
  - g. *All aspects of the study are conducted according to appropriate standards of scientific integrity.*
  - h. *The study has a written protocol that clearly demonstrates adherence to the standards listed here as Medicare requirements.*
  - i. *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.*
  - j. *The clinical research studies and registries are registered on the [www.ClinicalTrials.gov](http://www.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).*
  - k. *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](http://ClinicalTrials.gov), or in journals willing to publish in abbreviated format (e.g., for studies with negative or incomplete results).*
  - l. *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.*
  - m. *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.*

### **C. Nationally Non-Covered Indications**

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

*(This NCD last reviewed February 2016.)*