

Percutaneous Left Atrial Appendage Closure (LAAC)

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IMPORTANT REMINDER

The Medicare Advantage Medical Policy manual is not intended to override the member Evidence of Coverage (EOC), which defines the insured's benefits, nor is it intended to dictate how providers are to practice medicine. Physicians and other health care providers are expected to exercise their medical judgment in providing the most appropriate care for the individual member.

The Medicare Advantage Medical Policies are designed to provide guidance regarding the decision-making process for the coverage or non-coverage of services or procedures in accordance with the member EOC and the Centers of Medicare and Medicaid Services (CMS) policies, when available. In the event of a conflict, applicable CMS policy or EOC language will take precedence over the Medicare Advantage Medical Policy. In the absence of CMS guidance for a requested service or procedure, the health plan may apply their Medical Policy Manual or MCG™ criteria, both of which are developed with an objective, evidence-based process using scientific evidence, current generally accepted standards of medical practice, and authoritative clinical practice guidelines.

Medicare and EOCs exclude from coverage, among other things, services or procedures considered to be investigational, cosmetic, or not medically necessary, and in some cases, providers may bill members for these non-covered services or procedures. Providers are encouraged to inform members in advance when they may be financially responsible for the cost of non-covered or excluded services.

DESCRIPTION

“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.” (*Medicare NCD 20.34*)

MEDICARE ADVANTAGE POLICY CRITERIA

Note: “...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 the device has received Food and Drug Administration

(FDA) Premarket Approval (PMA) for that device’s FDA-approved indication and meets all the specified conditions...

“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.”^[1]

CMS Coverage Manuals* None

National Coverage Determinations (NCDs)* Percutaneous Left Atrial Appendage Closure (LAAC) ([20.34](#))

For Medicare-approved clinical trials and registries, visit the CMS LAAC [Coverage with Evidence Development](#) web page.

Note: The Participant Directory for facilities can be found on the ACC Quality Improvement for Institutions Program website: <https://cvquality.acc.org/NCDR-Home/participant-directory> .
(Look for those with the “LAAO Registry” noted under the “Registry” column.)

For FDA approved indications for various devices, see the FDA website.

POLICY GUIDELINES

REQUIRED DOCUMENTATION

The information below **must** be submitted for review to determine whether policy criteria are met. If any of these items are not submitted, it could impact our review and decision outcome:

- Name of device that will be used (FDA-approval information about the device would also be beneficial, but is not required);
- CHADS2 score;
- Documentation of shared decision-making with an independent non-interventional physician;
- The national, audited registry that (1) the patient is enrolled in and (2) the multidisciplinary team (MDT) and hospital are participants of (according to NCD 20.34, “LAAC is non-covered for the treatment of NVAf when not furnished under CED.” Therefore, this information is required for coverage to be approved);
- All medical records relevant to the condition being treated, and treatment plan.

REGULATORY STATUS

DEVICE	MANUFACTURER	FDA APPROVAL
DEVICES		
<i>Devices include, but may not be limited to, the following (not all may have FDA approval at this time)</i>		
The Watchman™ left atrial appendage system	Boston Scientific Corp.	2015
The Lariat® Loop Applicator	SentreHEART	2006 (510(k) process)
The Cardioblade® closure device	Medtronic	N/A (approved for septal defect, but not for LAA closure)
Amplatzer® cardiac plug	St. Jude Medical	N/A
The Percutaneous LAA Transcatheter Occlusion device	eV3	N/A
Atriclip™ LAA Exclusion System	AtriCure, Inc.	2014 (510(k) process)

CROSS REFERENCES

[Coverage with Evidence Development \(CED\) Studies and Registries](#), Medicine, Policy No. M-156

REFERENCES

1. MLN Matters® Number [MM9638](#), Dated May 6, 2016
2. Food and Drug Administration. 2014 [cited November 15, 2017]; Available from: http://www.accessdata.fda.gov/cdrh_docs/pdf14/K142120.pdf
3. Food and Drug Administration. 2015 [cited November 15, 2017]; Available from: https://www.accessdata.fda.gov/cdrh_docs/pdf13/p130013a.pdf
4. Food and Drug Administration. 2006 [cited November 15, 2017]; Available from: https://www.accessdata.fda.gov/cdrh_docs/pdf6/k060721.pdf

CODING

NOTE: Under Medicare instruction, claims for LAAC may be reported with the modifier -Q0.^[1] According to CMS, Medicare Advantage Organizations (MAOs) are responsible for processing LAAC claims. Therefore, they would not require a Medicare Explanation of Benefits (MEOB).

Codes	Number	Description
CPT	33340	Percutaneous transcatheter closure of the left atrial appendage with endocardial implant, including fluoroscopy, transseptal puncture, catheter placement(s), left atrial angiography, left atrial appendage angiography, when performed, and radiological supervision and interpretation
	93799	Unlisted cardiovascular service or procedure

Codes	Number	Description
HCPCS	None	

***IMPORTANT NOTE:** Medicare Advantage medical policies use the most current Medicare references available at the time the policy was developed. Links to Medicare references will take viewers to external websites outside of the health plan's web control as these sites are not maintained by the health plan.