CARDIAC DEVICES AND PROCEDURES FOR OCCLUSION OF THE LEFT ATRIAL APPENDAGE

Policy Number: 2016M0061B  Effective Date: May 1, 2016

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INSTRUCTIONS:

“Medical Policy assists in administering UCare benefits when making coverage determinations for members under our health benefit plans. When deciding coverage, all reviewers must first identify enrollee eligibility, federal and state legislation or regulatory guidance regarding benefit mandates, and the member specific Evidence of Coverage (EOC) document must be referenced prior to using the medical policies. In the event of a conflict, the enrollee’s specific benefit document and federal and state legislation and regulatory guidance supersede this Medical Policy. In the absence of benefit mandates or regulatory guidance that govern the service, procedure or treatment, or when the member’s EOC document is silent or not specific, medical policies help to clarify which healthcare services may or may not be covered. This Medical Policy is provided for informational purposes and does not constitute medical advice. In addition to medical policies, UCare also uses tools developed by third parties, such as the InterQual Guidelines®, to assist us in administering health benefits. The InterQual Guidelines are intended to be used in connection with the independent professional medical judgment of a qualified health care provider and do not constitute the practice of medicine or medical advice. Other Policies and Coverage Determination Guidelines may also apply. UCare reserves the right, in its sole discretion, to modify its Policies and Guidelines as necessary and to provide benefits otherwise excluded by medical policies when necessitated by operational considerations.”
POLICY DESCRIPTION:

This policy addresses the percutaneous approach for closure of the left atrial appendage when performed using cardiac occlusion devices, which are deployed under transesophageal echocardiographic or fluoroscopic guidance as a nonsurgical alternative to open heart surgery. The purpose of percutaneous left atrial appendage closure (LAA) is to replace the need for oral anticoagulation medication in the prevention of stroke in patients with nonvalvular permanent or paroxysmal atrial fibrillation (AF).

COVERAGE RATIONALE / CLINICAL CONSIDERATIONS:

The use of a cardiac device for occlusion of the left atrial appendage (e.g., The Amplatzer Cardiac Plug, The AtriClip System, The Lariat System, Cardioblate Closure Device, The PLAATO Device, The Watchman Device, etc.) is considered EXPERIMENTAL AND/OR INVESTIGATIONAL for the prevention of stroke and all other indications because their effectiveness for these indications has not been established.

Epicardial clipping of the left atrial appendage is considered EXPERIMENTAL AND/OR INVESTIGATIONAL for prevention of stroke and all other indications because its effectiveness for these indications has not been established.

Left atrial appendectomy is considered EXPERIMENTAL AND/OR INVESTIGATIONAL for prevention of stroke and all other indications because its effectiveness for these indications has not been established.

The Centers for Medicare & Medicaid Services (CMS), under certain conditions, covers percutaneous left atrial appendage closure (LAAC) for non-valvular atrial fibrillation (NVAF) through Coverage with Evidence Development (CED). Coverage with Evidence Development (CED) means that Medicare requires participation in certain clinical trials, longitudinal studies, or registries for coverage of an investigational item/service (e.g., LAAC) and routine and related items/services.


Note: For Medicare NCD and/or Medicare LCD, please consult CMS website at: https://www.cms.gov/medicare-coverage-database or National Government Services website at: https://www.ngsmedicare.com.

Clinical Considerations:

Patients usually take warfarin for approximately 45 days postimplantation to reduce the risk of thrombus formation on the implant during device endothelialization. Patients are transitioned to a regimen of aspirin and clopidogrel once warfarin is discontinued.

Limitations of Procedure: The limitations of percutaneous left atrial appendage closure (LAA) via trans-septal placement of devices such as the Watchman include:

- Requirement for anticoagulation and/or antithrombotic treatment during the procedure and for a short term (patients usually take warfarin for approximately 45 days postimplantation) until achievement of sufficient device endothelialization, precludes its use in patients with strict contradiction to
Clinical & Quality Management

MEDICAL POLICY

anticoagulation
- Insertion of a foreign body into the central circulation, which most likely introduces a low risk of embolization, erosion, and dislodgement
- Challenges of closely matching the size of the device to the LAA
- Presence of atrial septal defect closure might prevent transseptal implantation of the device

Possible Complications: Low-frequency, but serious, adverse events (e.g., severe pericardial effusions, procedure-related ischemic stroke, device embolization), including deaths, have been associated with implantation of these devices.

BACKGROUND:

Atrial fibrillation (AF) is an abnormal, supraventricular, accelerated heart rhythm (tachyarrhythmia), which leads to worsening atrial function and irregular ventricular conduction. Approximately one third of patients hospitalized for cardiac arrhythmias have AF, making it the most common arrhythmia detected in clinical practice. The most common form of AF in the United States is nonvalvular AF, which occurs without concomitant rheumatic mitral valve disease, a prosthetic heart valve, or mitral valve repair. Patients with AF have a significantly increased risk of stroke, heart failure, and death compared with patients with normal heart rhythms.

Ischemic stroke and other obstructions of arteries throughout the body in patients with AF is thought to be primarily caused by emboli (migrating blood clots) originating from the left atrium. To reduce the risk of stroke, patients with AF may be treated with long-term oral anticoagulation (e.g., warfarin) and/or antiplatelet agents (e.g., aspirin and/or clopidogrel) unless the bleeding risk posed by these medications outweighs their benefits in stroke prevention. Warfarin is the current standard pharmacological prevention for patients with nonvalvular atrial fibrillation. However, it is underutilized, has a narrow therapeutic window, and is associated with serious bleeding complications, and 15% to 60% of atrial fibrillation patients may be ineligible for warfarin therapy.

A critical initial step in determining patients’ individualized course of treatment is to estimate their stroke risk and risk of bleeding; this information helps in weighing the risk and benefits of antithrombotic therapy for primary stroke prevention. CHADS2 (cardiac failure, hypertension, age ≥ 75 years, diabetes, stroke) is a validated stroke prediction scheme that uses a point system for the presence of the various risk factors, allocating 2 points each for prior stroke or transient ischemic attack and 1 point each for age > 75 years, hypertension, diabetes, and heart failure. CHADS2 scores range from a low of 0 (1.9% adjusted annual stroke rate) to a high of 6 (18.2% adjusted annual stroke rate).

While anticoagulation treatment with warfarin is more effective than antiplatelet therapy for stroke prevention in patients with AF, its use is complicated by a limited therapeutic range, need for frequent monitoring, presence of multiple drug and food interactions, and risk of bleeding. Furthermore, some patients are not eligible for warfarin therapy because of allergic reactions to warfarin, severe liver disease, recent trauma, surgery, or active bleeding.

These issues have spurred the clinical development of new oral anticoagulants such as dabigatran, rivaroxaban, and apixaban. These drugs have shown noninferiority in efficacy compared with warfarin in randomized phase 3 clinical studies in patients with AF; they have not been compared with each other.
These newer anticoagulants appear to have some advantages relative to warfarin such as no food incompatibilities, fewer drug interactions, and no requirement for laboratory monitoring. The limitations of these new drugs include the lack of antidotes and specific blood assays to monitor their anticoagulation effects.

Problems with warfarin-based anticoagulation therapy have also spurred the development of nonpharmaceutical approaches to stroke reduction in patients with AF. The rationale for occluding the left atrial appendage (LAA) as an alternative to anticoagulation therapy is based on findings that thrombi (local blood clots) have been found in the LAA in approximately 90% of patients with nonvalvular (also called nonrheumatic) AF and 57% of patients with valvular (rheumatic) AF.

The LAA is a sac-like pouch attached to the left atrium where blood may pool during the incomplete contractions characteristic of atrial fibrillation. Therefore, it is thought that removing the LAA or excluding it from circulation may reduce the risk of stroke associated with atrial fibrillation.

The two main approaches used to occlude the LAA in clinical practice include: (1) surgical amputation or external occlusion via ligation in patients undergoing concurrent coronary artery bypass graft, mitral valve surgery, or epicardial ablation; (2) endocardial occlusion using a percutaneous transcatheter closure device. However, surgical LAA exclusion is challenging and success depends on surgeon skill and experience; staples or sutures have been associated with tearing and bleeding.

The general steps in the implantation procedure include measuring LAA dimensions by TEE and/or angiography to select the device size and exclude the presence of thrombi in the LAA (if present, procedure was discontinued); insertion of the device via percutaneous catheter; positioning and expansion of the device; performance of manual tests and/or imaging to evaluate the seal quality; release of the device from the catheter used for implantation; and additional imaging to determine if leaks are present. The devices are designed so that they can be recaptured for repositioning or removal if there are any problems during implantation (e.g., LAA anatomy precludes closure or requires use of a different size device).

Several versions of the devices have been developed. The WATCHMAN® left atrial appendage system (Boston Scientific, Maple Grove, MN) is a self-expanding nickel titanium device. It has a polyester covering and fixation barbs for attachment to the endocardium. Implantation is performed percutaneously through a catheter delivery system, utilizing venous access and transseptal puncture to enter the left atrium. Following implantation, patients are anticoagulated with warfarin or alternate agents for approximately one-two months. After this period, patients are maintained on antiplatelet agents (i.e., aspirin and/or clopidogrel) indefinitely. The Lariat® Loop Applicator is a suture delivery device that is intended to close a variety of surgical wounds in addition to left atrial appendage closure. The Cardioblate® closure device developed by Medtronic Corp. is currently being tested in clinical studies. The Amplatzer® septal closure device, manufactured by AGA Medical Corp, Plymouth, MN, is FDA-approved for closure of atrial septal defects. This device has also been used as a LAA closure device. A second-generation device, the Amplatzer Amulet, has been developed. The Percutaneous LAA Transcatheter Occlusion (PLATTO) device (eV3, Plymouth MN) has also been studied for this purpose but has not received FDA approval.

REGULATORY STATUS:

1. U.S. FOOD AND DRUG ADMINISTRATION (FDA):
Percutaneous left atrial appendage (LAA) closure is a surgical procedure and, therefore, is not subject
to FDA regulation. However, the devices designed for LAA occlusion using an endocardial approach are subject to FDA regulation. None of the existing available devices have received FDA approval with an indication of percutaneous LAA closure.

- **The WATCHMAN Device:**
The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) has given premarket approval (PMA) for the WATCHMAN LAA Closure Technology on March 13, 2015. This device is indicated to reduce the risk of thromboembolism from the left atrial appendage (LAA) in patients with non-valvular atrial fibrillation who:
  - Are at increased risk for stroke and systemic embolism based on CHADS2 or CHA2DS2-VASc scores and are recommended for anticoagulation therapy;
  - Are deemed by their physicians to be suitable for warfarin; and
  - Have an appropriate rationale to seek a non-pharmacologic alternative to warfarin, taking into account the safety and effectiveness of the device compared to warfarin.

Expiration dating for this device has been established and approved at 3 years. Continued approval of this PMA is contingent upon the submission of periodic reports, required under 21 CFR 814.84, at intervals of one year, unless otherwise specified, from the date of approval of the original PMA. Two copies of this report, identified as "Annual Report", should be submitted. This is a reminder that as of September 24, 2014, class III devices are subject to certain provisions of the final unique device investigation (UDI) rule. The Office of Device Evaluation (ODE) will have the lead for this clinical study, which was initiated prior to device approval. This study should be conducted per revision of the CAP protocol, revision of the PREVAIL protocol, and version AF of the CAP2 protocol. The study will consist of all IDE patients from PREVAIL, CAP, and CAP2 who are currently enrolled and alive.

The study objective is to characterize the safety and effectiveness of the WATCHMAN LAA Closure Technology annually through 5 years post-procedure. Failure to comply with any post-approval requirement constitutes a ground for withdrawal of approval of a PMA.

- **The LARIAT System:** (E.g., the Lariat snare device, the Lariat procedure) is manufactured and approved by the U.S. FDA for soft tissue closure ("approximation") only. It is not U.S. FDA approved for occlusion of the left atrial appendage (LAA). The LARIAT system is a lasso type of device that is guided into place by magnets, in order to encircle the left atrial appendage. After the magnets attach, the device is put in place and then tightened, which occludes the left appendage of blood flow, therefore facilitating a normalized heart blood flow.

- **The Cardioblate Closure Device:** Developed by Medtronic Corp. (Minneapolis, MN). This device is currently being tested in clinical studies.

- **The Amplatzer Cardiac Plug (ACP) Septal Closure Device:** Manufactured by AGA Medical Corp. (Plymouth, MN). The ACP is FDA-approved for closure of atrial septal defects. Although this device has also been used as a LAA closure device, this use has not received FDA approval.

- **The Atria Clip:** Manufactured by Atricure, Inc. (West Chester, OH). The AtriClip is made of two parallel rigid titanium tubes with elastic nitinol springs covered with a knit-braided polyester sheath. It is placed epicardially around the left atrial appendage and compresses the appendage at its base, excluding blood from entering the appendage.
The AtriClip received FDA 510(k) clearance (K093679) on June 10, 2010. According to the clearance summary: “...The AtriClip LAA Exclusion System is indicated for the occlusion of the left atrial appendage, under direct visualization, in conjunction with other open cardiac surgical procedures...”

- **Atricure Isolator System and Atricure’s Multifunctional Pen:** The FDA has cleared the AtriCure Isolator system and AtriCure’s multifunctional pen and Coolrail linear ablation device, for the ablation, or destruction, of cardiac tissue during surgical procedures.

The FDA has cleared AtriCure’s multifunctional pen for temporary pacing, sensing, stimulating and recording during the evaluation of cardiac arrhythmias and AtriCure’s Cryo1 system for the cryosurgical treatment of cardiac arrhythmias.

The U.S. FDA has not cleared or approved AtriCure’s products for the treatment of AF.

- **The Percutaneous LAA Transcatheter Occlusion (PLAATO) System:** Manufactured by ev3 Inc. (Plymouth, Minnesota). According to Leal et al. (2012), in 2006, the manufacturer discontinued development of this device because of a combination of financial problems and a concern with serious side effects reported in clinical practice (e.g., vessel perforation during vascular access, cardiac tamponade after transseptal puncture, and device embolization). A registry study of this device only mentioned the financial concerns as the reason for the manufacturer discontinuing its development. The device was composed of a self-expanding nitinol cage (made in sizes ranging from 15 to 32 mm in diameter) covered by a polytetrafluoroethylene material impermeable to blood. Another component of the system was the transseptal sheath used to deliver the device into the LAA. The size of the expanded device chosen for insertion was usually 20% to 50% larger than the orifice of the LAA, as measured by angiography and transesophageal echocardiography (TEE).

2. **CENTERS FOR MEDICARE AND MEDICAID SERVICES (CMS):**

Percutaneous left atrial appendage (LAA) Closure Therapy. CMS has released a NCD decision (NCD 15-003 and CAG-00445N, effective 2/9/16) adding coverage for percutaneous left atrial appendage closure (LAAC) for non-valvular atrial fibrillation through Coverage with Evidence Development (CED).

Note: Coverage with Evidence Development means that Medicare may require participation in certain clinical trials, longitudinal studies, or registries for coverage of an investigational item/service and routine and related items/services. All CED studies are listed on the CMS CED website.

3. **MINNESOTA DEPARTMENT OF HUMAN SERVICES (DHS):** Minnesota DHS does not have a policy statement regarding transcatheter closure of septal defects or left atrial appendage in its Provider Manual or other specific provider references.

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**CLINICAL EVIDENCE:**

This report evaluates data from the published clinical studies investigating the use of three different devices: PLAATO (ev3), Watchman (Boston Scientific), and Amplatzer (St. Jude Medical Inc.) for
percutaneous LAA closure to reduce stroke risk in patients with AF.

1. **EXTERNAL SOURCES/ GROUPS POLICY:**

   **American College of Cardiology, Heart Rhythm Society:** In 2015, the American College of Cardiology (ACC), Heart Rhythm Society (HRS), and Society for Cardiovascular Angiography and Interventions published an overview of the integration of percutaneous LAA closure devices into the clinical practice of patients with AF. The overview was organized around questions related to the sites of care delivery for LAA closure devices, training for proceduralists, necessary follow-up data collection, identification of appropriate patient cohorts, and reimbursement. The statement provides general guidelines for facility and operator requirements, including the presence of a multidisciplinary heart team, for centers performing percutaneous LAA closures. The statement does not provide specific recommendations about the indications and patient populations appropriate for percutaneous LAA closure.

   **American College of Cardiology/American Heart Association:** In 2014, the American College of Cardiology, the American Heart Association, and the Heart Rhythm Society issued guidelines on the management of patients with AF. These guidelines recommend that surgical excision of the LAA may be considered in patients undergoing cardiac surgery (Class IIB recommendation; Level of evidence: C), but make no specific recommendations regarding percutaneous LAA closure.

   **American College of Chest Physicians:** In 2012, the American College of Chest Physicians has evidence-based clinical best practice guidelines on the use of antithrombotic therapy for prevention of stroke in AF. In relation to the use of LAA closure devices, the guidelines state: “At this time, we make no formal recommendations regarding LAA closure devices, pending more definitive research in this field.”

   **European Society of Cardiology:** The update of the European Society of Cardiology (2012) guidelines for the management of AF makes a weak recommendation for the use of interventional, percutaneous LAA closure in patients with a high stroke risk and contraindication for long-term anticoagulation.

**SUMMARY:**

Left atrial appendage (LAA) occlusion devices are nonpharmacologic alternatives to anticoagulation for patients with atrial fibrillation. In the U.S., atrial fibrillation is the most prevalent sustained cardiac arrhythmia resulting in significantly greater risk of stroke due to migration of clots that may form in the LAA. As confirmed by echocardiography and autopsy, LAA is identified as a leading source of thrombi in individuals with non-valvular AF. By closing off the LAA, the occlusion device is designed to reduce risk of stroke and other cardiovascular complications.

Currently, the WATCHMAN® is the only FDA approved device for this indication in the U.S. Case series have demonstrated that these devices can be successfully implanted percutaneously in most patients. Complications such as pericardial effusion and tamponade are reported in available studies at a rate of 2-5%. Overall, the evidence on LAA devices is limited in quantity and quality, and device safety has not been established.

The LARIAT® Suture Delivery Device and Accessories provides another potential alternative to closure, currently being studied as an alternative to standard anticoagulation therapy.

Given the lack of U.S. FDA approval and the limited data regarding impact on net health outcomes, use of left atrial appendage closure devices is considered investigational. Large randomized controlled trials
(RCTs) are needed to determine whether percutaneous left atrial appendage (LAA) closure is effective and safe in reducing the risk of stroke in patients with nonvalvular atrial fibrillation (AF) compared with oral anticoagulation therapy (warfarin and the newer agents) in patients eligible for such therapy and compared with standard care in patients with contraindications to these medications. An RCT would also be helpful in comparing the safety and efficacy of the available devices. RCTs, cohort studies, and registry studies with longer follow-up are needed to assess the long-term safety, stability, and effectiveness of these devices in providing long-term protection from stroke. Studies are also needed to assess the frequency and long-term consequences of incomplete LAA closure following device implantation. Current data are not sufficient to help physicians and their patients weigh the risks and benefits of this procedure, including consideration of risk of stroke, risk of procedure, risk of bleeding, and desired quality of life.

**APPLICABLE CODES:**

The Current Procedural Terminology (CPT®) codes and HCPCS codes listed in this policy are for reference purposes only. Listing of a service or device code in this policy does not imply that the service described by this code is a covered or non-covered health service. The inclusion of a code does not imply any right to reimbursement or guarantee claims payment. Other medical policies and coverage determination guidelines may apply.

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<td>93318</td>
<td>Echocardiography, transesophageal (TEE) for monitoring purposes, including probe placement, real time 2-dimensional image acquisition and interpretation leading to ongoing (continuous) assessment of (dynamically changing) cardiac pumping function and to evaluate therapeutic</td>
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measures on an immediate time basis.

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<td>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</td>
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</tbody>
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CPT® is a registered trademark of the American Medical Association.

REFERENCES:


51. Leal S, Moreno R, de Sousa Almeida M, Silva J, López-Sendón J. Evidence-based percutaneous closure of the left


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<td>New policy 2012M0061A. Approved by the Medical Policy Committee.</td>
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<td>06/01/2014</td>
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