Medical Policy
Left Atrial Appendage Closure (LAAC) (Occlusion)

Policy Number: PG0366
Last Review: 11/01/2023

PARAMOUNT

HMO & PPO
MARKETPLACE
MEDICARE – ELITE, MAP

IMPORTANT | **Paramount medical policies only apply to Paramount Advantage Medicaid claims with dates of service before Feb. 1, 2023.** Please contact Anthem, for Medicaid claims with dates of service on or after Feb. 1, 2023.

GUIDELINES

- This policy does not certify benefits or authorization of benefits, which is designated by each individual policyholder terms, conditions, exclusions, and limitations contract. It does not constitute a contract or guarantee regarding coverage or reimbursement/payment. Self-Insured group specific policy will supersede this general policy when group supplementary plan document or individual plan decision directs otherwise.
- Paramount applies coding edits to all medical claims through coding logic software to evaluate the accuracy and adherence to accepted national standards.
- This medical policy is solely for guiding medical necessity and explaining correct procedure reporting used to assist in making coverage decisions and administering benefits.

SCOPE

X Professional
X Facility

DESCRIPTION

Atrial fibrillation (AF) is one of the most common cardiac arrhythmias and a leading cause of stroke. Individuals with AF have a higher risk for stroke due to the possibility of thrombus (blood clot) formation in coronary arteries. The left atrial appendage (LAA) of the heart was previously considered to have little purpose or activity; however, due to the shape of the appendage and lack of blood flow in the area, it is believed that thrombi could develop in certain individuals. While current standard treatment for nonvalvular AF focuses on anticoagulation; it is suggested that closure by exclusion or occlusion of the LAA may reduce the risk for embolic stroke from atrial thrombi. Exclusion of the LAA may be performed at the same time as another open cardiac surgical procedure.

The Watchman™ Left Atrial Appendage Closure Device (Boston Scientific, Maple Grove, MN) is a self-expanding nickel-titanium system. Implantation is performed percutaneously with a catheter delivery system, with venous access and trans-septal puncture to enter the left atrium. After implantation of device, patients receive anticoagulation with warfarin or other agents for approximately one to two months. During this acute period, anticoagulation may be necessary due to risk of thrombus formation related to altered blood flow around the implant. Patients are monitored with transesophageal echocardiography to assess blood flow and complete LAA closure (LAAC). After this period, patients will receive antiplatelet agents (e.g., aspirin and/or clopidogrel) indefinitely.

The Amplatzer™ Amulet™ (Abbott) is another FDA-approved percutaneously implanted LAA closure device that differs from the WATCHMAN devices in that it uses a dual seal mechanism to form a complete seal in the LAA opening and eliminates the need for post implantation anticoagulation. Dual antiplatelet therapy (may or may not be limited to aspirin and clopidogrel) is recommended for up to 6 months following the procedure.

Other available devices that have not received FDA approval for the use of LAA closure include:

- The Amplatzer™ Cardiac Plug (St. Jude Medical, Minneapolis, MN) is approved for LAAC in Europe. The device closes off the LAA in a manner similar to the Watchman. The technique for implanting this device is also similar to that of the Watchman™ system.
- The Lariat® Loop Applicator is a suture delivery device that is designed to close a variety of surgical wounds in addition to LAAC. The technical approach differs from that of the Watchman system. The Lariat suture loop ligates the LAA from the epicardial space, with assistance of catheters and balloons in the left atrium.
- The Percutaneous LAA Transcatheter Occlusion device (ev3) has also been evaluated in research studies but has not received FDA approval.
- The Occlutech® (Occlutech) Left Atrial Appendage Occluder has received a CE mark for coverage in Europe.
- The CardioblateTM closure device (Medtronic) is currently being tested in clinical studies.

POLICY

Paramount Commercial Insurance Plans and Medicare Advantage Plans

- **Left Atrial Appendage Closure (LAAC) (Occlusion)) does not require prior authorization, when the coverage criteria below are met, and**
- **The device is used according to FDA labeled indications, contraindications, warnings, and precautions**

COVERAGE CRITERIA

Paramount Commercial Insurance Plans and Medicare Advantage Plans

Paramount has determined that percutaneous endovascular closure (occlusion) of the left atrial appendage (LAA) is proven and medically necessary to reduce the risk of stroke when using a U.S. Food and Drug Administration (FDA) approved device, when all of the following criteria are met:

- A diagnosis of nonvalvular atrial fibrillation
- A percutaneous left atrial appendage closure (LAAC) device is used according to FDA labeled indications, contraindications, warnings, and precautions
- A CHADS2 score ≥ 2 (Congestive heart failure, Hypertension, Age > 75, Diabetes, Stroke/transient ischemiaattack/thromboembolism) or CHA2DS2-VASc score ≥ 3 (Congestive heart failure, Hypertension, Age ≥ 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 non-valvular atrial fibrillation (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 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.

Coverage Limitations:

Members may NOT be eligible under the Plan for percutaneous(transcatheter) LAA closure for the prevention of stroke for any indications other than those listed above including, but not limited to:

- Contraindications to the use of short-term anticoagulants (eg, warfarin) or long-term antiplatelet agents when indicated (eg, aspirin or clopidogrel; not an all-inclusive list)
- History of repair or use of closure device for PFO or atrial septal defect
- Intracardiac thrombus visualized by echocardiography
- Known sensitivity to any portion of the device material
- LAA anatomy will not accommodate a closure device
- Unsuitable for percutaneous catheterization due to any of the following, which may or may not be limited to:

- Active infection or bleeding disorder
- Body size unable to accommodate intracardiac echocardiography (ICE) transesophageal echocardiography (TEE) probe
- Peripheral access limited by size or condition (eg, peripheral vascular disease)

Paramount has determined that surgical closure (occlusion) of the LAA as part of cardiac surgery with cardiopulmonary bypass for a different indication (i.e., for the treatment of non-valvular atrial fibrillation) is proven and medically necessary to reduce the risk of stroke when all of the following criteria are met:

- Age 18 years or above
- History of atrial fibrillation
- CHA2DS2-VASc Score ≥ 2
- Device is used according to FDA labeled indications, contraindications, warnings, and precautions, when applicable

Coverage Limitations:
Members may not be eligible under the Plan for surgical (open) LAA closure for the prevention of stroke, in conjunction with other cardiac surgical procedures for any indications other than those listed above including, but not limited to:

- Contraindication to the use of short-term anticoagulants (eg, warfarin) or long-term antiplatelet agents (eg, aspirin or clopidogrel, not an all-inclusive list)
- History of repair or use of closure device for PFO
- Intracardiac thrombus visualized by echocardiography
- Known sensitivity to any portion of the device material
- LAA anatomy will not accommodate a closure device

CHA2DS2-VASc Score: Also known as the Birmingham schema, is a risk stratification score used to estimate the long-term systematic embolization risk in patients with atrial fibrillation.
2009 Birmingham Schema Expressed as a Point-Based Scoring system, with the Acronym CHA2DS2-VASc:

Risk Factor	Points
Congestive Heart Failure Associated signs and symptoms, or left ventricular systolic dysfunction	1
Hypertension	1
Age ≥ 75 years	2
Diabetes mellitus	1
Stroke, transient ischemic attack, or thromboembolism	2
Vascular Disease (prior myocardial infarction, peripheral artery disease or aortic plaque Myocardial infarction, peripheral artery disease, or aortic plaque	1
Age 65–74 years	1
Sex category (i.e., female gender)	1

The Left Atrial Appendage Closure (LAAC) (Occlusion) must be performed in a hospital with an established structural heart disease and/or electrophysiology program 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 two-year period.

Surgical left atrial appendage occlusion devices, for the treatment of stroke prevention in individuals with atrial fibrillation undergoing open or thoracoscopic cardiac procedures are considered experimental/investigational.

- Thoracoscopic closure (occlusion) of the LAA as a stand-alone procedure or as an adjunct to thoracoscopic atrial fibrillation ablation is unproven and not medically necessary due to insufficient evidence of safety and/or efficacy.
- Paramount considers exclusion of LAA (e.g., clip, excision, isolation via stapling, ligation, over-sewing, and plication) alone during open heart surgeries (i.e., not when used in conjunction with FDA-approved LAA closure device for the treatment of non-valvular atrial fibrillation) experimental/investigational and therefore non-covered.

CODING/BILLING INFORMATION

The inclusion or exclusion of a code in this section does not necessarily indicate coverage. Codes referenced in this clinical policy are for informational purposes only.
Codes that are covered may have selection criteria that must be met.
Payment for supplies may be included in payment for other services rendered.

CPT CODES	
33267	Exclusion of left atrial appendage, open, any method (e.g., excision, isolation via stapling, oversewing, ligation, plication, clip) [Considered Experimental/Investigational when used to report closure of the left atrial appendage NOT performed in conjunction with an open cardiac surgical procedure]
33268	Exclusion of left atrial appendage, open, performed at the time of other sternotomy or thoracotomy procedure(s), any method (e.g., excision, isolation via stapling, oversewing, ligation, plication, clip) (List separately in addition to code for primary procedure) [Considered Medically Necessary when criteria in the applicable policy statements listed above are met and when used to report surgical closure of the left atrial appendage, including use of a clip, for the prevention of stroke in conjunction with other cardiac procedures using a U.S. Food and Drug Administration (FDA) approved device]
33269	Exclusion of left atrial appendage, thoracoscopic, any method (e.g., excision, isolation via stapling, oversewing, ligation, plication, clip) [Considered Experimental/Investigational]
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
33999	Unlisted procedure, cardiac surgery

REVISION HISTORY EXPLANATION
ORIGINAL EFFECTIVE DATE: 04/22/2016

Date	Explanation & Changes
04/22/2016	• Policy created to reflect most current clinical evidence per The Technology Assessment Working Group (TAWG)
01/27/2017	• Effective 12/31/16 deleted code 0281T • Added effective 01/01/17 new code 33340 • Percutaneous Left Atrial Appendage Closure (LAAC) (33340) is now covered for Advantage • Percutaneous Left Atrial Appendage Closure (LAAC) (33340) no longer requires prior authorization • Policy reviewed and updated to reflect most current clinical evidence per The Technology Assessment Working Group (TAWG)
02/22/2018	• Policy reviewed and updated to reflect most current clinical evidence per The Technology Assessment Working Group (TAWG)
12/22/2020	• Medical policy placed on the new Paramount Medical Policy Format
02/28/2023	• Medical Policy updated to reflect Medicaid coverage to Anthem as of 02/01/2023
12/01/2023	• Medical Policy reviewed and updated to reflect the most current clinical evidence • Changed the medical policy name from Percutaneous Left Atrial Appendage Closure (LAAC) to Left Atrial Appendage Closure (LAAC) (Occlusion) • Added procedure codes 33267, 33268, and 33269

	• Removed deleted code 0218T • Updated the policy to include the scope of facility along with professional

Paramount reserves the right to review and revise our policies periodically when necessary. When there is an update, we will publish the most current policy to https://www.paramounthealthcare.com/providers/medical-policies/policy-library**.**

REFERENCES/RESOURCES

Centers for Medicare and Medicaid Services, CMS Manual System and other CMS publications and services https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Internet-Only-Manuals-IOMs

American Medical Association, *Current Procedural Terminology (CPT®)* and associated publications and services https://www.ama-assn.org/amaone/cpt-current-procedural-terminology

Centers for Medicare and Medicaid Services, Healthcare Common Procedure Coding System, HCPCS Release and Code Sets https://www.cms.gov/Medicare/Coding/HCPCSReleaseCodeSets/HCPCS-Quarterly-Update

Centers for Medicare & Medicaid Services (CMS), ICD-10-CM Official Guidelines for Coding and Reporting https://www.cms.gov/medicare/coding/icd10

Hayes, Inc.

Industry Standard Review

DESCRIPTION

Minimally invasive procedures for closure of the left atrial appendage (LAA) have been developed for the purpose of prevention of stroke. In an individual with atrial fibrillation (AF) there is a higher risk for blood clots to form which could lead to stroke. Percutaneous LAA closure devices are a non-pharmacologic alternative to anticoagulation for stroke prevention in AF. It is theorized that the devices may prevent thrombus formation and stroke by occluding the LAA.

The Watchman™ Left Atrial Appendage Closure Device (Boston Scientific, Maple Grove, MN) is a self-expanding nickel-titanium system. Implantation is performed percutaneously with a catheter delivery system, with venous access and trans-septal puncture to enter the left atrium. After implantation of device, patients receive anticoagulation with warfarin or other agents for approximately one to two months. During this acute period of time, anticoagulation may be necessary due to risk of thrombus formation related to altered blood flow around the implant. Patients are monitored with transesophageal echocardiography to assess blood flow and complete LAA closure (LAAC). After this period, patients will receive antiplatelet agents (e.g., aspirin and/or clopidogrel) indefinitely.

Other available devices that have not received FDA approval for the use of LAA closure include:

- The Amplatzer™ Cardiac Plug (St. Jude Medical, Minneapolis, MN) is approved for LAAC in Europe. The device closes off the LAA in a manner similar to the Watchman. The technique for implanting this device is also similar to that of the Watchman™ system.
- The Lariat® Loop Applicator is a suture delivery device that is designed to close a variety of surgical wounds in addition to LAAC. The technical approach differs from that of the Watchman system. The Lariat suture loop ligates the LAA from the epicardial space, with assistance of catheters and balloons in the left atrium.

POLICY

Paramount Commercial Insurance Plans, Medicare Advantage Plans, and Paramount Advantage Medicaid

Percutaneous Left Atrial Appendage Closure (LAAC) (33340) does not require prior authorization.

COVERAGE CRITERIA

Paramount Commercial Insurance Plans, Medicare Advantage Plans, and Paramount Advantage Medicaid

Paramount has determined that Percutaneous Left Atrial Appendage Closure (LAAC) devices (eg, the Watchman™) 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 formal shared decision-making interaction with an independent non-interventional physician using an evidence-based decision tool on oral anticoagulation in patients with non-valvular atrial fibrillation (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 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 ≥ 25 interventional cardiac procedures that involve transeptal puncture through an intact septum; and
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