HIGHMARK Delaware
HEALTH OPTIONS

CLINICAL MEDICAL POLICY	
Policy Name:	Percutaneous Left Atrial Appendage Closure (LAAC) Device
Policy Number:	MP-086-MD-DE
Responsible Department(s):	Medical Management
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Products:	Highmark Health Options Medicaid
Application:	All participating hospitals and providers
Page Number(s):	1 of 7

DISCLAIMER

Highmark Health Options medical policy is intended to serve only as a general reference resource regarding coverage for the services described. This policy does not constitute medical advice and is not intended to govern or otherwise influence medical decisions.

POLICY STATEMENT

Highmark Health Options may provide coverage under the medical-surgical benefits of the Company's Medicaid products for medically necessary Percutaneous Left Atrial Appendage Closure device.

This policy is designed to address medical necessity guidelines that are appropriate for the majority of individuals with a particular disease, illness or condition. Each person's unique clinical circumstances warrant individual consideration, based upon review of applicable medical records.

The qualifications of the policy will meet the standards of the National Committee for Quality Assurance (NCQA) and the Delaware Department of Health and Social Services (DHSS) and all applicable state and federal regulations.

DEFINITIONS

Atrial Fibrillation (AF) – A supraventricular, accelerated heart rhythm characterized by uncoordinated atrial activation that leads to inefficient, irregular atrial contraction.

Oral Anti-Coagulation (OAC) – Commonly referred to as blood thinners, chemical substances that prevent or reduce coagulation of blood, prolonging the clotting time.

Left Atrial Appendage (LAA) – A small, long, sac-like pocket located in the wall of the left atrium (top left chamber of the heart) that varies in size and shape.

Left Atrial Appendage Closure (LAAC) – A treatment strategy to reduce the risk of left atrial appendage blood clots from entering the bloodstream and causing a stroke in patients with nonvalvular atrial fibrillation (NVAF).

Nonvalvular Atrial Fibrillation (NVAF) – A heart rhythm disorder that causes a rapid and irregular heartbeat (arrhythmia) not due to an abnormal heart valve**.** NVAF is a type of atrial fibrillation (AF). During AF, electrical activity in the heart is disorganized, and the heart's blood flow is disrupted.

PROCEDURES

1. Medical Necessity Guidelines
   The use of an FDA-approved device for percutaneous left atrial appendage closure (LAAC) (e.g., the Watchman™) is considered medically necessary for the prevention of stroke in individuals with nonvalvular atrial fibrillation with documentation of ALL of the following:
   A. A CHADS2 score ≥ 2 (Congestive heart failure, Hypertension, Age > 75, Diabetes, Stroke/transient ischemia attack/thromboembolism); OR
   B. CHA2DS2-VASc score ≥ 3 (Congestive heart failure, Hypertension, Age ≥ 65, Diabetes, Stroke/transient ischemia attack/thromboembolism, Vascular disease, Sex category); AND
   C. 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; AND
   D. 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.

2. The percutaneous LAAC device (e.g., the Watchman™) must be performed by an interventional cardiologist(s), electrophysiologist(s), or cardiovascular surgeon (s) that meet the following criteria:
   A. Has received training prescribed by the manufacturer on the safe and effective use of the device prior to performing LAAC; AND
   B. Has performed ≥ 25 interventional cardiac procedures that involve transeptal puncture through an intact septum; AND

C. 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.

3. Contraindications
   The Watchman™ LAAC device is contraindicated for the following:
   A. Intracardiac thrombus is visualized by echocardiographic imaging;
   B. An atrial septal defect repair or closure device or a patent foramen ovale repair or closure device is present;
   C. The patient's LAA anatomy will not accommodate a device;
   D. Any of the customary contraindications for other percutaneous catheterization procedures (e.g., patient size too small to accommodate TEE probe or required catheters) or conditions (e.g., active infection, bleeding disorder) are present;
   E. There are contraindications to the use of warfarin, aspirin, or clopidogrel;
   F. The patient has a known hypersensitivity to any portion of the device material or the individual components (see Device Description section) such that the use of the Watchman™ device is contraindicated.

4. When the LAAC devices are not covered
   LAAC devices are not covered for conditions other than those listed above because the scientific evidence has not been established, including but not limited to:
   A. The use of Watchman™ LAAC device for stroke prevention in patients who do not meet the above criteria; OR
   B. The use of other percutaneous LAAC devices, including but not limited to:
      1) Lariat® devices; OR
      2) Amplatzer® devices; OR
      3) PLAATO; OR
      4) Cardioblate® devices; OR
      5) Occlutech®

   Note: Safety and/or effectiveness of these devices cannot be established by review of the available published peer-reviewed literature. Therefore use of these devices is considered experimental/investigational.

5. Post-payment Audit Statement
   The medical record must include documentation that reflects the medical necessity criteria and is subject to audit by Highmark Health Options at any time pursuant to the terms of your provider agreement.

6. Place of Service
   The place of service for the implantation of the Watchman™ LAAC device is in the outpatient setting.

GOVERNING BODIES APPROVAL

The Food and Drug Administration approved the Watchman™ LAA closure device as an alternative to anticoagulation for stroke prevention in atrial fibrillation (AF) in March 2015. The Watchman™ device is the only LAA closure device that is FDA-approved. The approval notes that the device is indicated to reduce the risk of thromboembolism from the LAA in patients with nonvalvular atrial fibrillation who:

- are at increased risk for stroke and systemic embolism based on CHADS2 (cardiac failure, hypertension, age = 75 years, diabetes, stroke) or CHA2DS2-VASc (congestive heart failure,

hypertension, age = 75 years, diabetes, stroke/transient ischemic attack/thromboembolism, vascular disease, aged 64 to 74 years, sex category {female}) scores and are recommended for anticoagulation therapy;
- are deemed by their physicians to be suitable for warfarin;
- have an appropriate rationale to seek a non-pharmacologic alternative to warfarin, taking into account the safety and effectiveness of the device compared to that of warfarin

Non-FDA-approved LAAC devices in the prevention of strokes in AF include but are not limited to:

- Amplatzer Amulet;
- 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 an LAA closure device, this use has not received FDA approval;
- Cardioblate® closure device: Developed by Medtronic Corp. (Minneapolis, MN). This device is currently being testing in clinical studies;
- Lariat® Loop Applicator: LAAC device 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);
- Occlutech® Left Atrial Appendage Occuluder

CODING REQUIREMENTS

Procedure Codes

CPT Code	Description
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

Diagnosis Codes

ICD-10 Codes	Description
I48.0	Paroxysmal atrial fibrillation
I48.1	Persistent atrial fibrillation
I48.2	Chronic atrial fibrillation
I48.91	Unspecified atrial fibrillation

REIMBURSEMENT

Participating facilities will be reimbursed per their Highmark Health Options contract.

SUMMARY OF LITERATURE

Atrial fibrillation (AF) due to valvular heart disease is an important cause of stroke and is conventionally treated with long-term oral anticoagulants that reduce the stroke risk. However, there are varying degrees of bleed risk associated with anticoagulation, and not everyone can tolerate taking anticoagulant medications as part of their daily routine (Hijazi, 2019). Among patients with Nonvalvular AF, the vast majority of thrombus material is located within or comprises the left atrial appendage (LAA). The intense fibrosis and inflammation in the left atrium of patients with AF, which are likely predisposing factors to

thrombus formation, are extreme in the LAA. The percutaneous left atrial appendage closure (LAAC) device is a nonpharmacological procedure that has been studied as an alternative for patients with AF.

The Watchman™ LAAC device is a catheter-based intervention. The medical advancement is a permanent implant device that can block blood flow going into the LAA during episodes of atrial fibrillation, prevent blot clot formation, avoid AF related stroke damage, and over time, remove the need for daily warfarin. The Watchman™ device is the only FDA-approved device.

The Watchman™ device is implanted in a minimally invasive procedure using a catheter, under general anesthesia. The procedure is performed in a catheterization laboratory setting and typically lasts an hour. It has been approved in Europe since 2005, and the device was granted U.S. Food and Drug Administration (FDA) approval in 2015.

Rationale

Clinical input obtained from the Department of Health Services Technology Assessment Group (TAG) concluded limited/minimal evidence of effectiveness with program exceptions, which indicates the development of criteria for the Watchman™ device. The meeting was held on May 1, 2019, and the final memo is pending publishing.

The Watchman™ device was evaluated in two randomized trials (PROTECT AF and PREVAIL) in patients with Nonvalvular AF eligible for oral anticoagulation (Reddy, Doshi, et al., 2017).

- One trial (PROTECT AF) was a noninferiority trial in which 707 patients were randomly assigned in a 2:1 ratio to either the device or to long-term warfarin. Inclusion criteria allowed for patients with paroxysmal, persistent, or permanent AF and all patients has a CHADS2 score ≥ 1. There was a significant decline in the rate of procedure or device-related safety events within seven days compared with those in the randomized trial. This report raises the possibility of improved outcomes with device implantation with increased operator experience. In addition to the safety benefits, a retrospective review of 6- and 12-month follow-up echocardiograms showed no significant increase in the rate of thromboembolism in the patients with incomplete LAA sealing compared with those without. It is likely that most residual holes are small and not associated with embolization of large clots. The quality of life improved at 12 months for patients treated with the closure device, while the quality of life declined among the patients treated with warfarin.

  The following findings were noted from the PROTECT AF trial:
  - After a mean follow-up of 18 months, the primary efficacy event rate was similar in the intervention and control groups. After a mean follow-up of 2.3 years, the primary efficacy event rates were 3.0 and 4.3 percent, respectively. These results allowed for a finding of noninferiority of the device with its specific antithrombotic protocol compared to warfarin.
  - The primary safety end point occurred significantly more often in the device group. Most of the events in the device group occurred early. Of these, about 50 percent were pericardial effusions requiring drainage. The device embolization rate was 0.6 percent.
  - At a mean follow-up of 3.8 years, the primary efficacy rate remained similar in both groups. There was also a 60 percent relative risk reduction of cardiovascular death with Watchman™, which was predominantly driven by a significant reduction in hemorrhage stroke.

- The second trial (PREVAIL) was mandated by the U.S. FDA to further evaluate the safety profile and confirm the efficacy of the Watchman™ device for regulatory approval. This study randomly assigned 407 patients in a 2:1 ratio to Watchman™ or warfarin. Inclusion criteria were CHADS2 score ≥ 2, or

CHADS2=1, if ≥ 1 if the following were present: female is ≥ 75 years old, left ventricular ejection fraction 30 to 34.9 percent, age 65 to 74 with diabetes or coronary artery disease, or age ≥ 65 with documented congestive heart failure (CHF). These patients must be able to tolerate warfarin for at least six weeks after the device is implanted and cannot have LAA clot present at the time of implantation.

The following findings were noted from the PREVAIL trial:

- At 18-month follow-up, the first co-primary efficacy end point (composite of stroke, systemic embolism, and cardiovascular/unexplained death) was 0.064 with Watchman™ versus 0.063, and did not achieve the pre-specified noninferiority criteria. The second co-primary efficacy end point (stroke or systemic embolism > 7 days post-randomization) was 0.025 versus 0.020, achieving noninferiority.

Based upon the results of PROTECT AF and PREVAIL, the Watchman™ device was approved by the United States FDA in March 2015 for patients with nonvalvular AF for whom long-term anticoagulation is indicated, but who have a sensible reason to not take such therapy.

Hayes (2018) has established the following ratings for this technology:

- Hayes Rating of "C": For use of the Watchman™ device to reduce the risk of stroke in adult patients with NVAF. This rating reflects moderate-quality evidence suggesting a potential benefit of treatment compared with OAC therapy but also substantial uncertainty regarding the risk for device-related complications and mortality. This rating also reflects the lack of comparative effectiveness data for Watchman™ versus newer OAC therapies and the lack of long-term efficacy data regarding LAA closure.
- Hayes Rating of "D^2": For use of the Amplatzer Cardiac Plug (ACP) and Amplatzer Amulet devices in LAA closure to reduce the risk of stroke in adult patients with NVAF. This rating reflects the low-quality evidence and lack of evidence from randomized controlled trials on the long-term safety, efficacy in LAA closure, and effectiveness in stroke prevention of these devices for this indication.
- Hayes Rating of "D^2": For use of the Lariat Suture Delivery Device in LAA closure to reduce the risk of stroke in adult patients with NVAF. This rating reflects the paucity of evidence regarding the safety, efficacy in LAA closure, and effectiveness in stroke prevention of Lariat for this indication.

Among societal research, the American Heart Association/American College of Cardiology/Heart Rhythm Society updated 2014 guidelines for the management of patients with atrial fibrillation (January, 2019). The societies made a weak recommendation for surgical excision of LAA at the time of cardiac surgery. In addition, it states the percutaneous LAA occlusion may be considered in patients with AF that are at an increased risk of stroke with contraindications to long-term anticoagulation.

On May 21, 2015, the Centers for Medicare & Medicaid Services (CMS) accepted a request from Boston Scientific Corporation to initiate a National Coverage Analysis (NCA) for percutaneous LAA closure using the implantable Watchman™ LAAC device.

POLICY SOURCE(S)

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Policy History

Date	Activity
05/03/2019	Initial policy developed
07/16/2019	QI/UM Committee approval
09/16/2019	Provider effective date