WATCHMAN™ LEFT ATRIAL APPENDAGE CLOSURE
Approval/Coverage Status & Clinical Evidence Summary

FDA Approved on March 13, 2015

The WATCHMAN Left Atrial Appendage Closure (LAAC) implant procedure received FDA approval on March 13, 2015 and has been established as safe and effective for treating patients within its approved indication. The device is indicated to reduce the risk of thromboembolism from the left atrial appendage in patients with non-valvular atrial fibrillation who:

- Are at increased risk for stroke and systemic embolism based on CHADS$_2$ or CHA$_2$DS$_2$-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.

CMS National Coverage Determination established February 8, 2016

CMS finalized a National Coverage Determination for percutaneous LAAC (20.34) on February 8, 2016. The NCD establishes uniform coverage and access to the WATCHMAN Device for Medicare beneficiaries who meet specific patient criteria, including:

- A CHADS$_2$ score ≥ 2 or CHA$_2$DS$_2$-VASc score ≥ 3
- A suitability for short-term warfarin but deemed unable to take long term oral anticoagulation
- Documented evidence of a formal shared decision-making interaction between the patient and an independent non-interventional physician using an evidence-based decision tool on oral anticoagulation.


2019 AHA/ACC/HRS Guideline for the Management of Patients with Atrial Fibrillation

The 2019 AHA/ACC/HRS Focused Update of the 2014 AHA/ACC/HRS Guideline for the Management of Patients with Atrial Fibrillation recommends Percutaneous LAAO therapy as a Class IIb therapy and LOE B-NR.

The guidelines state that Percutaneous LAAO may be considered in patients with AF at increased risk of stroke who have contraindications to long-term anticoagulation. The updated guidelines specifically note that the Watchman device provides an alternative for patients who are poor candidates for long-term oral anticoagulation (because of the propensity for bleeding or poor drug tolerance or adherence). The guidelines are consistent with and reinforce WATCHMAN’s labeling and the CMS coverage decision which support the use of WATCHMAN as an option for AF patients at an increased risk of stroke who have relative contraindications to long-term anticoagulation.

Clinical Condition and Treatment Options

Atrial fibrillation (AF) is the most common cardiac arrhythmia, currently affecting more than 5 million Americans. In AF, the left atrium does not beat - instead it fibrillates meaning that it barely moves. Because of this, AF patients have a five-fold increased risk of stroke due to blood pooling in the left atrium and left atrial appendage (LAA). The pooled blood can form blood clots (i.e., thrombus formation), which can break off and go into the systemic circulation and lodge somewhere else in the body. Most commonly, these clots will lodge in the brain causing a stroke. Ninety-one percent of left atrial thrombi in non-valvular atrial fibrillation have been shown
to be isolated to, or originate in, the LAA. The most common treatment for reducing the risk of these strokes from forming is using oral anticoagulants. Warfarin has been used for many years and works by interfering with the body’s clot forming mechanisms. Despite its proven efficacy, long-term warfarin therapy is not well-tolerated by some patients, has a very narrow therapeutic range, and carries a high risk for bleeding complications.

**WATCHMAN Left Atrial Appendage Closure**

The WATCHMAN Left Atrial Appendage Closure Device is a first-of-its-kind, proven alternative to long-term warfarin for stroke risk reduction in patients with non-valvular atrial fibrillation. WATCHMAN is the most studied LAAC device in the world and is the only one with long-term data from randomized trials and prospective, multicenter registries.

The WATCHMAN Device is indicated to reduce the risk of thromboembolism from the left atrial appendage 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.

The WATCHMAN Left Atrial Appendage is an implant that acts as a physical barrier, sealing the LAA to prevent thromboemboli from entering into the arterial circulation from the LAA, thereby reducing the risk of stroke and potentially eliminating the need for warfarin therapy in those patients with non-valvular AF who are eligible for warfarin. Implant of the WATCHMAN Device is performed under general anesthesia in a cardiac catheterization laboratory. The WATCHMAN Device is implanted percutaneously via a transcatheter approach, using a standard transseptal technique.

**Clinical Evidence**

The WATCHMAN clinical program consists of five prospective investigational studies (PILOT, PROTECT AF, CAP, PREVAIL, and CAP2) which include more than 2,400 patients implanted and >8,000 patient-years of follow-up regarding WATCHMAN™ Device performance. Final, five-year results from the PROTECT AF, CAP and PREVAIL studies have been published and/or presented. These long-term data continue to demonstrate the WATCHMAN Device is a safe alternative to long-term warfarin therapy which offers comparable stroke risk reduction and enables patients to stop taking warfarin.

The PILOT study enrolled the first clinical study patient in 2002 and proved the safety and feasibility of WATCHMAN™ implant. The prospective randomized study PROTECT AF enrolled the first clinical study patient in 2005 and was published in the *Lancet* in August 2009 with a mean follow-up of 18 months. The efficacy results were very compelling in that 87% of patients were successfully implanted with the device and able to discontinue warfarin therapy 45 days post-implant. Patients in the device group also had a 38% lower risk of stroke, systemic embolism, and cardiovascular or unexplained death when compared to patients treated with warfarin alone. Several subsequent analyses have been performed over the course of follow-up and continue to demonstrate a durable benefit in primary efficacy event reduction.

Next, the prospective, multi-center Continued Access to PROTECT AF (CAP) Registry enrolled the first trial patient in 2009 and enrolled a total of 566 patients using the same inclusion and exclusion criteria as the PROTECT AF study. These patients have completed all study follow-up (mean 4.2 years) with final results presented at the Transcatheter Cardiovascular Therapeutics conference in 2017 and published in *JACC*. Ninety-four percent (94%) of patients in the study were successfully implanted and procedure complications were significant reduced when compared to the PROTECT AF experience. In addition, 96% of patients discontinued...
warfarin after 45 days post-implant. While there was not a warfarin control arm as a comparator in the study, the rate of ischemic strokes in CAP was similar to the rate seen in the PROTECT AF device arm (1.2 vs 1.4 per 100 patient years, respectively).

The cadence and growing body of clinical evidence continues to support the medical value and safety of the WATCHMAN™ implant therapy. The PREVAIL randomized control study enrolled its first patient in 2012, all patients have completed the required follow-up (mean 4.0 years). First results were published in 2014 in JACC and support that WATCHMAN™ was successfully implanted with low complication rates and no differences in procedure-related events between new and experienced operators. Since the device was approved by the FDA in March of 2015, procedural safety data for both new and experience operators continues to show consistent results between 1.5% and 2% for major serious adverse events.

Furthermore, PREVAIL also showed that 92% of patients were able to discontinue warfarin therapy 45 days post implant, and >99% were able to discontinue warfarin therapy after 12 months.

Because the efficacy endpoint of the trial used a Bayesian statistical model that incorporated a portion of the PROTECT AF results, efficacy results for PREVAIL are presented in conjunction with PROTECT AF in order to fully describe the effect of LAAC therapy compared to warfarin. As a result, a patient-level meta-analysis using the final results of both randomized trials and were published in 2017 in JACC. The 5-Year Patient-Level Meta-Analysis of PROTECT AF and PREVAIL (2:1 Randomization) provided the totality of the evidence from both randomized trials for the WATCHMAN™ therapy after study required follow-up was completed for both randomized trials. This analysis demonstrated that LAAC with WATCHMAN provided stroke reduction in non-valvular atrial fibrillation patients that was comparable to warfarin with additional, statistically significant reductions in disabling or fatal stroke, hemorrhagic stroke, cardiovascular and all-cause mortality, as well as major non-procedure related bleeding.

The totality of the clinical evidence of WATCHMAN™ reinforces the following clinical outcomes: 

- A reduction of 18% (p=0.27) in all-cause stroke, systemic embolism and cardiovascular/unexplained mortality
- Comparable to warfarin for stroke, with statistically significant reductions by 55% in disabling/fatal stroke (p=0.03) and an 80% reduction in hemorrhagic strokes (p=0.002)
- Statistically significant reductions in all-cause and CV/unexplained mortality respectively 27% (P=0.04) and 41% (p=0.03)
- 72% reduction in major bleeding >6 months post-procedure vs warfarin

The WATCHMAN™ Device is the only FDA approved device for percutaneous left atrial appendage closure and is the most studied LAAC device in the world. WATCHMAN is the only LAAC device with long-term clinical data from both randomized clinical trial and prospective, multi-center registries, with five-year follow-up data on the majority of patients. These long-term data demonstrate that the WATCHMAN™ Device is a safe alternative to long-term warfarin therapy which offers comparable stroke risk reduction and enables patients to stop taking warfarin.

References


Important Information – Disclaimer

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Brief Summary Statement (BSS)

Overview

**Product:** Watchman LAA Closure Dev w Del Sys – DFU 90746221

**Rx Statement:** Include the following with every Brief Summary Statement:

**CAUTION:** Federal law (USA) restricts this device to sale by or on the order of a physician. Rx only. Prior to use, please see the complete “Directions for Use” for more information on Indications, Contraindications, Warnings, Precautions, Adverse Events, and Operator’s Instructions.

Content

**INDICATIONS FOR USE**

The WATCHMAN Device is indicated to reduce the risk of thromboembolism from the left atrial appendage 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.

**CONTRAINDICATIONS**

Do not use the WATCHMAN Device if:

- Intracardiac thrombus is visualized by echocardiographic imaging.
- An atrial septal defect repair or closure device or a patent foramen ovale repair or closure device is present.
- The LAA anatomy will not accommodate a device. See Table 46 (in the DFU).
- 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.
- There are contraindications to the use of warfarin, aspirin, or clopidogrel.
- 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.

**WARNINGS**

- Device selection should be based on accurate LAA measurements obtained using fluoro and ultrasound guidance (TEE recommended) in multiple angles (e.g., 0º, 45º, 90º, 135º).
- Do not release the WATCHMAN Device from the core wire if the device does not meet all release criteria.
- If thrombus is observed on the device, warfarin therapy is recommended until resolution of thrombus is demonstrated by TEE.
- The potential for device embolization exists with cardioversion <30 days following device implantation. Verify device position post-cardioversion during this period.
- Administer appropriate endocarditis prophylaxis for 6 months following device implantation. The decision to continue endocarditis prophylaxis beyond 6 months is at physician discretion.
- For single use only. Do not reuse, reprocess or resterilize.

**PRECAUTIONS**

- The safety and effectiveness (and benefit-risk profile) of the WATCHMAN Device has not been established in patients for whom long-term anticoagulation is determined to be contraindicated.
- The LAA is a thin-walled structure. Use caution when accessing the LAA and deploying the device.
- Use caution when introducing the WATCHMAN Access System to prevent damage to cardiac structures.
- Use caution when introducing the Delivery System to prevent damage to cardiac structures.
- To prevent damage to the Delivery Catheter or device, do not allow the WATCHMAN Device to protrude beyond the distal tip of the Delivery Catheter when inserting the Delivery System into the Access Sheath.
- If using a power injector, the maximum pressure should not exceed 100 psi.
- In view of the concerns that were raised by the RE-ALIGN study of dabigatran in the presence of prosthetic mechanical heart valves, caution should be used when prescribing oral anticoagulants other than warfarin in patients treated with the WATCHMAN Device. The WATCHMAN Device has only been evaluated with the use of warfarin post-device implantation.

**ADVERSE EVENTS**
Potential adverse events (in alphabetical order) which may be associated with the use of a left atrial appendage closure device or implantation procedure include but are not limited to:

- Air embolism
- Airway trauma
- Allergic reaction to contrast media/medications or device materials
- Altered mental status
- Anemia requiring transfusion
- Anesthesia risks
- Angina
- Anoxic encephalopathy
- Arrhythmias
- Atrial septal defect
- AV fistula
- Bruising, hematoma or seroma
- Cardiac perforation
- Chest pain/discomfort
- Confusion post procedure
- Congestive heart failure
- Contrast related nephropathy
- Cranial bleed
- Decreased hemoglobin
- Deep vein thrombosis
- Death
- Device embolism
- Device fracture
- Device thrombosis
- Edema
- Excessive bleeding
- Fever
- Groin pain
- Groin puncture bleed
- Hematuria
- Hemoptysis
- Hypotension
- Hypoxia
- Improper wound healing
- Inability to reposition, recapture, or retrieve the device
- Infection / pneumonia
- Interatrial septum thrombus
- Intratracheal bleeding
- Major bleeding requiring transfusion
- Misplacement of the device / improper seal of the appendage / movement of device from appendage wall
- Myocardial erosion
- Nausea
- Oral bleeding
- Pericardial effusion / tamponade
- Pleural effusion
- Prolonged bleeding from a laceration
- Pseudoaneurysm
- Pulmonary edema
- Renal failure
- Respiratory insufficiency / failure
- Surgical removal of the device
- Stroke – Ischemic
- Stroke – Hemorrhagic
- Systemic embolism
- TEE complications (throat pain, bleeding, esophageal trauma)
- Thrombocytopenia
- Thrombosis
- Transient ischemic attack (TIA)
- Valvular damage
- Vasovagal reactions

There may be other potential adverse events that are unforeseen at this time.

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