WATCHMAN

PHYSICIAN PEER-TO-PEER APPEAL GUIDE:

WATCHMAN LEFT ATRIAL APPENDAGE CLOSURE (LAAC) DEVICE

For questions regarding WATCHMAN™ reimbursement, please contact:

Email: WATCHMAN.Reimbursement@bsci.com

Please go to www.watchmandownloadcenter.com to access a sample prior authorization template.

The FDA Approved the WATCHMAN™ on March 13, 2015 and on July 21, 2020 they approved WATCHMAN FLX™

To access the percutaneous LAAC (WATCHMAN™ and WATCHMAN FLX™) approval document, visit the FDA website

WATCHMAN™
LEFT ATRIAL APPENDAGE CLOSURE DEVICE

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.

INDICATIONS FOR USE

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 present.
- 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 47 (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 echocardiographic imaging guidance (TEE recommended) in multiple angles (e.g., 0°, 45°, 90°, 135°).
- 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 the WATCHMAN Implant or implantation procedure include but are not limited to: air embolism, airway trauma, allergic reaction to contrast media, anesthetic, WATCHMAN Implant material, or medications, altered mental status, anemia requiring transfusion, anesthesia risk, angina, anoxic encephalopathy, arrhythmias, atrial septal defect, bruising, hematoma or seroma near the catheter insertion site, cardiac perforation, chest pain/discomfort, confusion post procedure, congestive heart failure, contrast related nephropathy, cranial bleed, death, decreased hemoglobin, deep vein thrombosis, device embolism, device fracture, device thrombosis, edema, embolism, excessive bleeding, fever, fistula, 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 – hemorrhagic, stroke – ischemic, systemic embolism, TEE complications (throat pain, bleeding, esophageal trauma), thrombocytopenia, thrombosis, transient ischemic attack (TIA), valvular or vascular damage, vasovagal reactions.

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

1 Eikelboom JW, Connolly SJ, Brueckmann M, et al. N Engl J Med 2013;369:1206-14.

IMPORTANT INFORMATION – DISCLAIMER

Health economic and reimbursement information provided by Boston Scientific Corporation is gathered from third-party sources and is subject to change without notice as a result of complex and frequently changing laws, regulations, rules and policies. This information is presented for illustrative purposes only and does not constitute reimbursement or legal advice. Boston Scientific encourages providers to submit accurate and appropriate claims for services. It is always the provider's responsibility to determine medical necessity, the proper site for delivery of any services and to submit appropriate codes, charges, and modifiers for services that are rendered. Boston Scientific recommends that you consult with your payers, reimbursement specialists and/or legal counsel regarding coding, coverage and reimbursement matters. It is always the provider's responsibility to understand and comply with national coverage determinations (NCD), local coverage determinations (LCD) and any other coverage requirements established by relevant payers which can be updated frequently.

Payer policies will vary and should be verified prior to treatment for limitations on diagnosis, coding or site of service requirements. The coding options listed within this guide are commonly used codes and are not intended to be an all-inclusive list. We recommend consulting your relevant manuals for appropriate coding options.

PHYSICIAN PEER-TO-PEER APPEAL GUIDE:

WATCHMAN LEFT ATRIAL APPENDAGE CLOSURE (LAAC) DEVICE

This guide is intended to support peer-to-peer appeal conversations between the implanting physician and health plan Medical Directors following a pre-procedural denial of coverage for the WATCHMAN (LAAC) Device implant procedure.

STEP 1 UNDERSTAND THE DENIAL

- Anticipate denials from insurers that have not yet established positive coverage policies for WATCHMAN LAAC Device implants.
- Review the reason for denial, as well as the payer-specific process for appealing pre-procedural denials.

STEP 2 QUALIFY THE REVIEWER

- If the plan does not have a positive coverage policy in place, start by confirming that the payer representative to whom you are speaking has the authority to overturn the denial by making a patient-specific exception to the current policy. If not, your time spent advocating will not be productive. Request a peer-to-peer review by an individual who has this authority.
- Verify the reviewer's medical specialty and understanding of stroke management and atrial fibrillation treatment options. If the reviewer is not familiar with this specialty area, consider requesting a "like-specialty peer-to-peer review", which indicates that you wish to speak with a physician of similar training, such as a Cardiologist, Interventional Cardiologist or Electrophysiologist.

STEP 3 REVIEW STATUS OF FDA APPROVAL, CMS AND COMMERCIAL COVERAGE

FDA Approval

The FDA Approved the WATCHMAN™ on March 13, 2015 and on July 21, 2020 they approved WATCHMAN FLX™

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https://www.accessdata.fda.gov/cdrh_docs/pdf13/P130013S035A.pdf

According to FDA Labeling: WATCHMAN LAA Closure Technology 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 $CHADS_2$ or CHA_2DS_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

Effective February 8th, 2016, Centers for Medicare and Medicaid Services (CMS) established a National Coverage Determination (NCD) for Percutaneous Left Atrial Appendage Closure (LAAC) (20.34). Details regarding requirements for coverage are provided on the CMS website at National Coverage Determination for Left Atrial Appendage Closure (20.34). This policy provides patient access to WATCHMAN LAAC for all Medicare beneficiaries, including those covered by Medicare Advantage plans.

PHYSICIAN PEER-TO-PEER APPEAL GUIDE

Continued

Under the CMS NCD, primary medical criteria for coverage are as follows:

- A $CHADS_2$ score ≥2 (Congestive heart failure, Hypertension, Age > 75, Diabetes, Stroke/transient ischemia attack/thromboembolism) or CHA_2DS_2-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 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.

STEP 4 FOCUS ON SECURING COVERAGE FOR AN INDIVIDUAL PATIENT

- The goal is to obtain one-time access to the WATCHMAN LAAC therapy by requesting a patient-specific exception to current policy. This is not the appropriate forum to advocate for a change in policy.
- Present evidence to demonstrate that your patient is a candidate for the WATCHMAN (LAAC) Device.
  - Reference the specific indication from the payer's policy.
  - If no written policy exists, reference indications within the Medicare National Coverage Determination (NCD) for LAAC .
  - Refer to established clinical guidelines from the key physician societies American College of Cardiology, Heart Rhythm Society, and The Society for Cardiovascular Angiography and Interventions. The three national societies jointly advocated in support of coverage with Centers for Medicare and Medicaid Coverage for the Left Atrial Appendage Closure Therapy in patients with non-valvular atrial fibrillation and as an alternative to warfarin for stroke prevention.
- Focus discussion on the specific patient's need for a WATCHMAN (LAAC) Device. Demonstrate that the patient meets FDA labeling requirements and highlight patient-specific reasons for seeking a non-pharmacologic alternative to warfarin, such as:
  - Patient has non-valvular atrial fibrillation and has a history of major bleeding while taking therapeutic anticoagulation therapy.
  - Patient is unable to maintain a stable INR or comply with regular INR monitoring over the long term, placing him/her at heightened risk of a thrombotic or bleeding event.

- Patient's occupation or lifestyle places him/her at high risk of major bleeding secondary due to trauma, and therefore has a reason to seek a non-pharmacologic alternative to long-term anticoagulation.

STEP 5 SUPPORT WITH CLINICAL EVIDENCE

A complete clinical evidence summary is available at watchmandownloadcenter.com by clicking on the "Reimbursement" tab, and selecting WATCHMAN Approval/Coverage Status and Clinical Evidence.

Please reach out to the Boston Scientific Health Economics and Market Access team with questions related to specific payer denials.

Watchman.Reimbursement@bsci.com

STEP 6 DETERMINE NEXT STEPS

If the reviewer denies the appeal by deferring to a non-coverage policy, request information regarding next steps for a for an expedited internal appeal.