WATCHMAN FLX LAAC DEVICE PHYSICIAN PEER-TO-PEER APPEAL GUIDE:

WATCHMAN FLX LAAC DEVICE

For questions regarding WATCHMAN FLX LAAC Device reimbursement, please contact:

Email: WATCHMAN.Reimbursement@bsci.com

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

The FDA Approved the WATCHMAN FLX LAAC Device on July 21, 2020.

To access the WATCHMAN FLX LAAC Device approval document, visit the FDA website

WATCHMAN FLX™ – eIFU 51221704

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 "Instructions for Use" for more information on Indications, Contraindications, Warnings, Precautions, Adverse Events, and Operator's Instructions.

INTENDED USE/INDICATIONS FOR USE

The WATCHMAN FLX 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 anticoagulation therapy; and
- Have an appropriate rationale to seek a non-pharmacologic alternative to anticoagulation therapy, taking into account the safety and effectiveness of the device compared to anticoagulation therapy.

CONTRAINDICATIONS

Do not use the WATCHMAN FLX 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 Closure Device (see **Table 45** of the eIFU).
- The patient has a known hypersensitivity to any portion of the device material or the individual components (see Device Description section of the eIFU) such that the use of the WATCHMAN FLX Device is contraindicated.
- Any of the customary contraindications for other percutaneous catheterization procedure (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 anticoagulation therapy, aspirin, or P2Y12 inhibitor.

WARNINGS

Implantation of the WATCHMAN FLX Device should only be performed by interventional cardiologists and/or electrophysiologists who are trained in percutaneous and transseptal procedures and who have completed the WATCHMAN FLX Physician Training program.

- This device has not been studied in pregnant or breastfeeding women. Careful consideration should be given to use of the Closure Device in pregnant and/ or breastfeeding women due to the risk of significant exposure to x-rays and the use of anticoagulation medication.
- Device selection should be based on accurate LAA measurements obtained using echocardiographic imaging guidance in multiple views (TEE recommended in multiple angles [e.g., 0°, 45°, 90°, 135°]) to avoid improper Closure Device sizing.
- Do not release (i.e., unscrew) the WATCHMAN FLX Device from the core wire unless all release criteria are satisfied to avoid suboptimal results.
- Potential for Closure Device embolization exists with cardioversion < 30 days following Closure Device implantation; verify Closure Device position after cardioversion during this period.
- Appropriate post-procedure drug therapy should be followed. See Post-Procedure Information section (of the eIFU) for further detail.

PRECAUTIONS

- The safety and effectiveness (and benefit-risk profile) of the WATCHMAN FLX 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, recapturing, and repositioning the Closure Device.
- Use caution when introducing a 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 Closure Device, do not allow the WATCHMAN FLX 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.

PATIENT SELECTION FOR TREATMENT

In considering the use of the WATCHMAN FLX Device, the rationale for seeking an alternative to long-term anticoagulation therapy and the safety and effectiveness of the device compared to anticoagulation should be taken into account.

- The presence of indication(s) for long-term anticoagulation therapy, other than non-valvular atrial fibrillation (e.g. mechanical heart valve, hypercoagulable states, recurrent deep venous thrombosis).

Details regarding the indications, contraindications, warnings, and precautions for oral anticoagulants approved for patients with non-valvular atrial fibrillation are provided in their respective Instructions for Use.

Of note:

- The safety and effectiveness (and benefit-risk profile) of the WATCHMAN FLX Device has not been established in patients for whom long-term anticoagulation is determined to be contraindicated.

Factors that need to be considered for the WATCHMAN FLX Device and implantation procedure include the following:

- Overall medical status, including conditions which might preclude the safety of a percutaneous, transcatheter procedure.
- Suitability for percutaneous, transseptal procedures, including considerations of:
  - Cardiac anatomy relating to the LAA size and shape.
  - Vascular access anatomy (e.g., femoral vein size, thrombus, or tortuosity).
  - Ability of the patient to tolerate general or local anesthesia.
  - Ability of the patient to undergo required imaging.
- Ability to comply with the recommended post-WATCHMAN FLX Device implant pharmacologic regimen (see Post-Procedure Information section) especially for patients at high risk for bleeding.

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 the contrast media, anesthetic, WATCHMAN Implant material, or medications, Altered mental status, Anemia requiring transfusion, Anesthesia risks, 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, Stroke – Hemorrhagic, Stroke – Ischemic, Surgical removal of the device, TEE complications (e.g., 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.

PHYSICIAN PEER-TO-PEER APPEAL GUIDE:

WATCHMAN FLX 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 FLX LAAC Device procedure.

STEP 1 UNDERSTAND THE DENIAL

- Anticipate denials from insurers that have not yet established positive coverage policies for WATCHMAN FLX LAAC Device.
- 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.

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

FDA Approval

The FDA Approved the WATCHMAN FLX LAAC Device on July 21, 2020.

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

To access the WATCHMAN FLX LAAC Device approval document, visit the FDA website

According to FDA Labeling: WATCHMAN FLX LAAC 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 $CHADS_2$ 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 FLX LAAC Device for all Medicare beneficiaries, including those covered by Medicare Advantage plans.

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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.

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STEP 4 FOCUS ON SECURING COVERAGE FOR AN INDIVIDUAL PATIENT

- The goal is to obtain one-time access to the WATCHMAN FLX LAAC Device 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 FLX 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 FLX 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.

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- 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.