WATCHMAN
SUPPORTING PATIENT ACCESS

The following information is provided to assist providers in addressing patient-specific insurance requirements for the WATCHMAN LAAC implant procedure and associated services.

Boston Scientific Reimbursement Support Line Addresses questions regarding appropriate coding, documentation and payer coverage policies.

Email: WATCHMAN.reimbursement@bsci.com

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.

SUPPORTING PATIENT ACCESS

STEP 1 DETERMINE INSURANCE COVERAGE

Coverage is dependent of the individual's health plan coverage and benefits.

Original Medicare

Original Medicare beneficiaries have access to the Left Atrial Appendage Closure procedure with the WATCHMAN device under a National Coverage Decision: NCD CED 20.34.

Medicare Advantage

Medicare Advantage Health plans are administered by Medicare Advantage Organizations (MAO). MAO plans are required to offer the same coverage as Original Medicare, however MAOs conduct a medical necessity review through Utilization Management (UM). The review for medical necessity may take up to two weeks. The MAO is required to communicate their decision to the provider and patient in writing.

Medicaid

Medicaid plans vary with respect to their coverage of the WATCHMAN LAAC Therapy. You may contact the Boston Scientific Reimbursement Support Line for information regarding state-specific coverage status.

Commercial Insurance

Patients often obtain health insurance from their employer, or purchase through an exchange. Commercial health insurance contractually requires prior authorization before services are rendered. The Commercial Health Insurance reviews applicable data and reviews for medical necessity. Their determination is communicated to the provider and patient in writing. This process can take up to two weeks.

STEP 2 REQUEST PRIOR-AUTHORIZATION OR PRE-DETERMINATION

The prior-authorization process involves obtaining advance notification from the health plan that medical necessity and other coverage criteria have been met as set forth by the payer.

- Boston Scientific encourages providers to seek WATCHMAN LAAC procedure prior-authorization or pre-determination for patients covered by commercial policies.
- Traditional Medicare does not require or accept prior-authorization requests.

If the plan does not have an established positive coverage policy for LAAC, anticipate a denial and be prepared to appeal (see STEP THREE). Many insurers will grant approvals on a case-by-case basis, following appeal.

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

- The prior-authorization process for elective procedures (including LAAC) typically takes 2+ weeks, not including time for appeals. BSC therefore recommends that providers allow at least three weeks for prior-authorization approvals, or delay scheduling until prior-authorization is confirmed. Urgency with respect to expedited approval may be communicated to the payer as deemed appropriate.

SUPPORTING PATIENT ACCESS

Continued

It is suggested to include the following information within the prior authorization submission:

- Patient insurance information: Name, ID and phone number (provide a front/back copy of patient's insurance card)
- Letter of Medical Necessity, edited and signed, to include:
  - Medical rationale describing the patient-specific benefits of WATCHMAN LAAC as an alternative to long-term anticoagulation therapy for stroke risk reduction
  - History and Physical (H&P), office/hospital notes, previous cardiac-related procedures, relevant clinical documentation
  - Risk of stroke based on $CHADS_2$ or CHA_2DS_2-VASc scores
  - List of current diagnoses (ICD-10) diagnosis codes may include:
    - I48.91 – Unspecified atrial fibrillation
    - I48.21 – Permanent atrial fibrillation
    - I48.0 – Paroxysmal atrial fibrillation
    - I48.11 – Longstanding persistent atrial fibrillation
    - I48.19 – Other persistent atrial fibrillation
  - Relevant procedure codes (CPT code 33340; ICD-10-CM procedure code 02L73DK)
  - Documentation of past anticoagulation-related complications, fall risk, inability to maintain a stable therapeutic International Normalized Ratio (INR), or a medical condition, occupation or lifestyle placing the patient at high risk of major bleeding
  - Documentation that the patient can tolerate OAC/warfarin therapy post-op for up to 6 weeks

STEP 3 APPEAL PRIOR-AUTHORIZATION DENIAL

Commercial Plan

Plans that do not have an established coverage policy may consider LAAC to be experimental and investigational, and deny coverage as a result. Providers/patients have the option to seek case-by-case coverage by requesting an exception to the policy.

Best Practices for Appealing a Commercial Plan Denial:

- Ask for clarification regarding the reason for the denial… is it due to documentation, patient criteria, or coverage? The insurer will communicate their decision for the prior authorization decision.
- Review the denial to prepare an appropriate response to the insurer's request and initiate the appeals process in accordance with the insurer's defined processes.
- Request a peer-to-peer review with a like-specialty physician (i.e. a Cardiologist, Interventional Cardiologist or Electrophysiologist). Plans are obligated to provide participating providers with the opportunity to speak with a qualified physician to request an exception to the coverage policy on a case-by-case basis.
- Provide the patient with options for advocating on their own behalf
  - Patient may submit a personal letter to accompany the doctor's appeal.
  - Patients can engage the plan directly with an appeal

SUPPORTING PATIENT ACCESS

Continued

Medicare Advantage

All Medicare beneficiaries have access to WATCHMAN LAAC Therapy under the CMS National Coverage Determination (20.34). Denials from Medicare Advantage plans may still occur however, as not all commercial plans maintain current information regarding Medicare coverage status. If coverage is denied for a Medicare beneficiary, provide information regarding CMS coverage policy 20.34 (available at www.cms.gov) to support an appeal.

Medicaid

Medicaid plans vary with respect to their coverage of the WATCHMAN LAAC Therapy. You may contact the Boston Scientific Reimbursement Support Line for information regarding state-specific requirements and the process for appealing denials.

STEP 4 ENGAGE IN INTERNAL APPEAL

To prepare for a successful Internal Appeal, investigate the reason for the denial.

Discuss whether it is due to documentation issues, patient criteria or coverage. Make sure to prepare comments that directly address insurer's reason for denial.

Best Practices for Internal Appeals:

- Include information about FDA approval and CMS National Coverage Determination. A summary of clinical evidence can be found here:
- Reference the indication from the payer's policy. If no written policy exists, reference the coverage criteria according to the CMS NCD (link). As appropriate, detail how the patient meets these indications for coverage.
- Provide compelling patient-specific reasons why the individual would benefit from LAAC, including details regarding past anticoagulation-related complications, fall risk, inability to maintain a stable therapeutic International Normalized Ratio (INR), or a medical condition, occupation or lifestyle placing the patient at high risk of major bleeding
- Reference available peer-reviewed publications that demonstrate the benefits of LAAC for indicated patients.
- Reference established coverage status for LAAC under other commercial plans.
- Expedited Internal appeals can be requested with a cardiologist that has experience with the WATCHMAN device.

STEP 5 EXTERNAL APPEAL

External Review

A patient has the right to take their appeal to an independent third party for review. This is called an external review. External review means that the insurance company no longer gets the final say over whether to pay a claim.

If the Health Insurance company maintains their denial, the final decision is communicated to the provider and patient in writing. The documentation is required to provide contact data for an external appeal.

Types of denials that can go to external review:

1) Any denial that involves medical judgment where the patient or provider may disagree with the health insurance plan.

2) Any denial that involves a determination that a treatment is experimental or investigational.

3) Cancellation of coverage based on the insurer's claim that a patient gave false or incomplete information when they applied for coverage.

What are a patient's rights in an external review?

Insurance companies in all states must offer an external review process that meets the federal consumer protection standards.

State

A state may have an external review process that meets or goes beyond these standards. If so, insurance companies in the state will follow the state's external review processes. A patient will get all the protections outlined in that process.

Federal

If a state doesn't have an external review process that meets the minimum consumer protection standards, the federal government's Department of Health and Human Services (HHS) will oversee an external review process for health insurance companies in that state. Depending on the plan and location, the following may apply to the patient:

- In states where the federal government oversees the process, insurance companies may choose to participate in an HHS-administered process or contract with independent review organizations.
- If the plan doesn't participate in a state or HHS-Administered Federal External Review Process, the health plan must contract with an independent review organization.

How to learn more about a state's external review?

Look at the information on your Explanation of Benefits (EOB) or on the final denial of the internal appeal by the health plan. The EOB will provide contact information for the organization that will handle your external review.

There may be exceptions with regards to Self-Insured Non-Federal Governmental Health Plans and Health Insurance Issuers Offering Group and Individual Health Coverage Using the HHS Administered Federal External Review Process

THE CENTER FOR CONSUMER INFORMATION & INSURANCE OVERSIGHT

Consumers' Rights to Appeal Health Plan Decisions

Under the Affordable Care Act, consumers have the right to appeal decisions made by health plans created after March 23, 2010. The law governs how insurance companies handle initial appeals and how consumers can request a reconsideration of a decision to deny payment. If an insurance company upholds its decision to deny payment, the law provides consumers with the right to appeal the decisions to an outside, independent decision-maker, regardless of the type of insurance or state an individual lives in.

https://www.cms.gov/CCIIO/Programs-and-Initiatives/Consumer-Support-and-Information/External-Appeals

The Employee Retirement Income Security Act of 1974 (ERISA) is a federal law that sets minimum standards for most voluntarily established retirement and health plans in private industry to provide protection for individuals in these plans.

ERISA requires plans to provide participants with plan information including important information about plan features; requires plans to establish a grievance and appeals process for participants to get benefits from their plans.

https://www.dol.gov/general/topic/retirement/erisa

REFERENCES AND RESOURCES

1 CPT ©2017 American Medical Association. All rights reserved. CPT is a registered trademark of the American Medical Association. Applicable FARS/DFARS Restrictions Apply to Government Use. Fee schedules, relative value units, conversion factors, and/or related components are not assigned by the AMA, are not part of CPT®, and the AMA is not recommending their use. The AMA does not directly or indirectly practice medicine or dispense medical services. The AMA assumes no liability for data contained or not contained herein.

2 American Medical Association: 2017 ICD-10-PCS for Hospitals – The Complete Official Draft Code Set, Professional Edition, Chicago, IL.

WATCHMAN™
LEFT ATRIAL APPENDAGE CLOSURE DEVICE