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

Voicemail: (877) 786-1050
Press 2 to leave a message. Messages are monitored M-F, 8am — 4pm CT and responses are typically on the same or following business day.

Phone (toll free): (877) 786-1050
Press 1 to connect with WATCHMAN Prior Authorization or Appeal support.

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

WATCHMAN™
LEFT ATRIAL APPENDAGE CLOSURE DEVICE

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.

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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 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 PMA application for the WATCHMAN Device on March 13, 2015. The FDA has posted the Integrated Summary of Safety and Effectiveness Data (SSED), the approval, Implant System Directions for Use, and the Patient Guide on its website at FDA Approval Order Statement.

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.

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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.

Commercial Coverage

Positive coverage policies for WATCHMAN LAAC have been established by over 30 national and regional health plans representing over 80 million covered lives. Examples include: Humana, TRICARE, BCBS FEP, Health Net, AmeriHealth and numerous BCBS Licensees. A complete list of plans that provide coverage for WATCHMAN LAAC is available at www.watchmandownloadcenter.com click on Reimbursement to access “WATCHMAN Private Payer List”.

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

Key Clinical Benefits include:

- 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

NOTE: A complete evidence summary is available at www.watchmandownloadcenter.com click on Reimbursement to access to "Approval/Coverage Status and Clinical Evidence Summary".

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 second appeal.