GUIDEPOINT Reimbursement Resources

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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 denial of coverage for the WATCHMAN (LAAC) Device.

1. Understand the Denial

- The insurer will communicate their decision for the prior authorization decision. Because of non-coverage policies for the WATCHMAN (LAAC) Device, denials.
- The provider should review the denial to best respond to the insurer's request and initiate the appeals process. Most insurers have a defined appeals process for pre-procedural denials so it is important to understand this process and request written recourse as soon as possible.
- Utilize the peer-to-peer review process as a potential option in the appeals process for presenting the medical necessity for a WATCHMAN (LAAC) Device.

2. Evaluate the Reviewer in the Peer-to-Peer Process

- Is the reviewer a Medical Director for the health plan or contracted reviewer?
- What is the reviewer's medical specialty, training, current understanding of stroke management and atrial fibrillation treatment options?
- What is the reviewer's willingness and authority to approve the procedure?
- If you find that this reviewer is not familiar with stroke patients or treatment of atrial fibrillation, asking for a "like peer-to-peer review" will indicate to the health plan that you wish to speak with a physician of similar training, such as a Cardiologist, Interventional Cardiologist or Electrophysiologist.

3. Stay on Point

- Present evidence that your patient is a candidate for a WATCHMAN (LAAC) Device. Reference the specific indication from the payer's policy or the Medicare National Coverage Determination (NCD) for LAAC if no written policy exists. Also, 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.[1]

- Focus discussion on the specific patient's need for a WATCHMAN (LAAC) Device. Specific scenarios that may support medical necessity include but are not limited to the following:
    - My patient has non-valvular atrial fibrillation and is having trouble tolerating their OAC and has a history of major bleeding while taking therapeutic anticoagulation therapy. My patient has an inability to maintain a stable INR, comply with regular INR monitoring and unavailability of an approved alternative anticoagulation agent. My patient's medical condition, occupation, or lifestyle places him/her at high risk of major bleeding secondary due to trauma (provide details- presence of indications(s) for long-term warfarin use, other than non-valvular atrial fibrillation (e.g. mechanical heart valve, hypercoagulable states, recurrent deep venous thrombosis).
- If the reviewer defers to the coverage policy, offer assistance and support in working through that process. Ask the reviewer for tangible next steps in the process. Is it a second round of appeals, or would it be possible for the case to be reviewed by an independent review organization (IRO)?
- Regardless of where the discussion goes, redirect the talk track back to the immediate need, which is an exception to current policy for a patient whose condition requires it. Insurers make exceptions to their non-coverage policies all the time, why should this be different?

4. Paint the Clinical Picture

- Point out, if accurate, that the patient currently meets the indications for coverage under the NCD for Left Atrial Appendage Closure Therapy and the WATCHMAN (LAAC) Device is the only device on the market with FDA approval. Further describe how the patient would further benefit from the WATCHMAN (LAAC) Device.
- What characteristics does the patient exhibit that would make the patient a candidate for the WATCHMAN (LAAC) Device such as their increased risk for stroke and systemic embolism based on their $CHADS_2$ or CHA_2 DS_2 – VASc score or rationale to seek a non-pharmacologic alternative to warfarin.
- Present evidence of the benefits of the WATCHMAN (LAAC) Device, such as:
    - Safely and effectively reduces stroke risk in patients with non-valvular atrial fibrillation.
    - The WATCHMAN (LAAC) Device is a one-time implant
    - 92% of patients are able to discontinue warfarin at 45 days post implant.
    - Avoids certain potential complications associated with long-term use of warfarin and major bleeds.
    - The WATCHMAN (LAAC) Device reduces hemorrhagic strokes, which are more often fatal and disabling (Protect AF).

5. State the Evidence – Executive Summary

Atrial fibrillation is the most common sustained arrhythmia and is associated with a significantly increased risk of thromboembolic stroke. Current pharmacologic therapies to reduce this risk have important limitations for many patients. A substantial number of high risk patients with non-valvular AF

[1] 2015 ACC/HRS/SCAI left atrial appendage closure device societal overview. American College of Cardiology; clinical guidelines and documents.

who are deemed suitable for anticoagulant therapy nonetheless have an appropriate rationale to seek a non-pharmacologic alternative and many of these patients, including many non-Medicare beneficiaries, are currently left unprotected from the potentially devastating consequences of stroke. The clinical community urgently needs a safe and effective alternative to oral anticoagulation to reduce the risk of cardioembolic stroke in these patients.

The WATCHMAN (LAAC) Device is the most comprehensively studied device supporting the reduction of cardioembolic stroke originating in the LAA. The totality of data from PROTECT AF, PREVAIL, and two continued access registries (CAP and CAP2) provides reasonable assurance of the safety and efficacy of WATCHMAN versus warfarin. WATCHMAN offers your members a safe and effective alternative to oral anticoagulation to reduce the risk of cardioembolic stroke in patients described above.

Meta-Analysis

A meta-analysis of TTR in AF patients treated with warfarin in the ambulatory setting in the US demonstrated AF patients spend, on average, only about one-half of the time within therapeutic INR in community practice, with average TTR = 51% (95% CI=47%-55%).[2] It is sobering to recognize that this average TTR achieved in real-world clinical practice represents a value that has been associated with limited or no efficacy of warfarin. In a post hoc analysis, the TTRs of patients on warfarin in a randomized trial of OAC versus dual antiplatelet therapy (clopidogrel plus aspirin)[3] were used to calculate the mean TTR for each of 526 centers and 15 countries. A wide variation was found to exist in TTR. A target threshold TTR was identified (estimated between 58% and 65%) below which there appears to be little benefit of OAC over antiplatelet therapy.

- In a systematic examination of clinical studies, TTR in retrospective studies was median 59% (29-75%), and in prospective cohort studies 61% (56-66%).[4]

- In the context of a large, integrated health system (i.e. the VA), TTR has been assessed as a basis for quality measurement and quality improvement efforts. The mean TTR for the entire sample was 58%.[5]

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: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P130013

[2] Baker WL, Cios DA, Sander SD, Coleman CI. Meta-analysis to assess the quality of warfarin control in atrial fibrillation patients in the United States. *J Manag Care Pharm*. 2009;15(3):244-52

[3]Connolly SJ, Pogue J, Eikelboom J, et.al. Benefit of oral anticoagulant over antiplatelet therapy in atrial fibrillation depends on the quality of International Normalized Ratio control achieved by centers and countries as measured by time in therapeutic range. *Circulation*. 2008;118:2029-37.

[4] Wan Y, Heneghan C, Perera R, et al. Anticoagulation control and prediction of adverse events in patients with atrial fibrillation: a systematic review. *Circ Cardiovasc Qual Outcomes*. 2008;1:84-91.

[5] Rose AJ, et al. Risk-adjusted percent time in therapeutic range as a quality indicator for outpatient oral anticoagulation: results of the Veterans Affairs Study to Improve Anticoagulation (VARIA). *Circ Cardiovasc Qual Outcomes*. 2011; 4:22-9.

Section 5 of this dossier contains the Integrated Summary of Safety and Effectiveness Data, the Indications for Use and the Patient Guide. The indications for use are as follows:

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.

6. State The Risks of Not Receiving WATCHMAN Device

- Provide patient's clinical background and risks associated with long-term use of OACs as well as the potential for complications.
- Restate and emphasize medical appropriateness for your patient.

7. Reference Commercial Health Plan & Medicare Coverage

While we recognize that the primary patient demographic for LAAC with the WATCHMAN (LAAC) Device has historically been, and will likely continue to be Medicare beneficiaries, to date, over 32 health plans have established positive coverage policies for LAAC, positively impacting over 80 million covered lives. These plans include the vast majority of the independent BCBS licensees, Medicaid, TRICARE, BCBS FEP, Health Net, and AmeriHealth.

- BCBS AR, AZ, FL, KS, LA, MA, MI, MS, NC, NJ, PA, RI, TN, WY
- BCBS – Carefirst
- BCBS – Federal Employee Program
- BCBS – HCSC
- BCBS – HealthNow
- Blue Cross – Capital
- Blue Cross of ID
- Blue Cross – Premera
- Blue Shield of CA
- Group Health
- Hawaii Medical Services Association
- Health Alliance
- HealthNet
- Medicaid AL, AZ, CT, GA, IN, IA, ME, MD, MI, MO, MT, NV, NM, SC, SD, VA, WI, WY
- Paramount Healthcare
- Priority Health
- Tricare
- Tufts Health Plan

CMS National Coverage Determination (NCD)

Effective February 8th, 2016, Centers for Medicare and Medicaid Services (CMS) approved Boston Scientific's request for a National Coverage Determination (NCD) for Percutaneous Left Atrial Appendage Closure (LAAC) (20.34) with certain criteria set forth in the NCD which must be met in order for a beneficiary to meet requirements for coverage. The primary medical criteria for coverage are as follows:

- A CHADS2 score ≥2 (Congestive heart failure, Hypertension, Age > 75, Diabetes, Stroke/transient ischemia attack/thromboembolism) or CHA2DS2-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.

Other requirements for coverage are facility/operator specific and outlined in the National Coverage Determination for Left Atrial Appendage Closure (20.34).

Current Procedural Terminology (CPT) Coding

Effective January 1st, 2017, American Medical Association (AMA) established Category I CPT 33340 as the permanent code for LAAC. As defined: *Percutaneous transcatheter closure of the left atrial appendage with endocardial implant, including fluoroscopy, transseptal puncture, catheter placement, left atrial angiography, left atrial appendage angiography, when performed, and radiological supervision and interpretation.*

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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.