

2017

**WATCHMAN Left Atrial Appendage Closure Device
(The WATCHMAN™ Device) Coding Guide- Structural Heart**

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***CMS establishes coverage for WATCHMAN under NCD 20.34 for percutaneous
Left atrial appendage closure (LAAC) therapy!***

Boston Scientific is pleased to announce that CMS has finalized the national coverage determination (NCD) for percutaneous LAAC therapy which provides coverage for WATCHMAN when specific conditions are met. The effective date of the NCD is Feb. 8, 2016.

To access the NCD in its entirety, please go to the [CMS website](#) or see page 3 of the Guide.

Reimbursement Overview

The table below provides an overview of coding, coverage and payment for the WATCHMAN™ Left Atrial Appendage Closure (LAAC) Therapy across sites-of-service and by payer.

	Coding	Medicare		Private Payer	
		Coverage	Payment	Coverage	Payment
Hospital Inpatient	ICD-10 procedure code 02L73DK*	NCD for percutaneous LAAC therapy effective on Feb 8, 2016	Most common mappings are MS-DRG 273 or 274	Varies by Payer policy for LAAC procedures- check with specific payer	Dependent on payer contract
Hospital Outpatient	CPT code 33340	Designated as "Inpatient Only"	NA	Check with specific payer	Payer specific
Physician	CPT code 33340	NCD for percutaneous LAAC therapy effective on Feb 8, 2016	Per the Medicare Physician's Fee Schedule	Refer to payer policy for LAAC procedures	Dependent on payer contract

National Coverage Determination (NCD 20.34)

On February 8, 2016, CMS issued the [final decision memo](#) that supports a national coverage determination (NCD) for Medicare beneficiaries undergoing Percutaneous Left Atrial Appendage (LAAC) Closure Therapy. [NCD 20.34](#) outlines specific criteria for WATCHMAN eligibility.

The criteria focus primarily on eligible patients, formal shared decision making, operator and infrastructure requirements, and submission of certain data to a national registry for LAAC procedures. The criteria are highlighted below (bolded for emphasis) and we encourage providers to read the decision memo in its entirety for additional detail.

- Eligible patients must have a **CHADS₂ score ≥ 2 or a CHA₂DS₂-VASc score ≥ 3**.
- There must be documented evidence of a formal **shared decision interaction between the patient and an independent, non-interventional physician using an evidenced-based decision making tool on oral anticoagulants**.
 - CMS references the following decision-making tools:
<http://guidance.nice.org.uk/CG180/PatientDecisionAid/pdf/English>
http://www.acponline.org/patients_families/products/brochures/afib_booklet.pdf
 - The American College of Cardiology provides tools that may also be useful: :
<http://www.acc.org/tools-and-practice-support/quality-programs/anticoagulation-initiative/anticoagulation-shared-decision-making-tool>
<https://www.acponline.org/practice-resources/patient-education/resources>
- Patients **must be suitable for short-term warfarin, but deemed unable to take long-term oral anticoagulation**.
- The procedure must be **performed in a hospital with an established structural heart disease or electrophysiology program**.
- The procedure must be **performed by an interventional cardiologist or electrophysiologist or cardiovascular surgeon** meeting the following criteria:
 - Trained by the manufacturer
 - **≥ 25 interventional cardiac procedures involving transseptal punctures through an intact septum**
 - Continues to perform ≥ 25 interventional cardiac procedures involving transseptal punctures through an intact septum, with at least 12 being LAAC over a two year period
- Patients **must be enrolled in a prospective national registry**.

CMS has certified the LAAO Registry™ (NCT02699957) as the national registry for data collection for LAAC procedures. The long-term data collection supports CMS's coverage with evidence development (CED) to ensure better visibility of safety and effectiveness of LAAC procedures.. The registry certification announcement is located at: <https://www.cms.gov/Medicare/Coverage/Coverage-with-Evidence-Development/index.html>. Hospitals performing WATCHMAN™ must contact the National Cardiovascular Data Registry (NCDR®) at ncdr@acc.org or 1-800-257-4737 to enroll in the LAAO Registry™.

Physician Reimbursement

Physician Coding

WATCHMAN Procedure

Effective January 1, 2017, physicians will report the WATCHMAN implant procedure using the CPT Code 33340. The work relative value unit (RVU) for this code is 14.00 with a total RVU of 23.22. The global period for this code is 0 days.

CPT Code	Description
33340	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

Based on CMS billing instructions, physician claims will need to have the following items to support the NCD for percutaneous LAAC procedures.¹ For dates of service on or after February 8th (the NCD effective date), physician claims will be processed only when billed with the following codes:

- CPT 33340
- Primary ICD-10 diagnosis code (one of the following):
 - 148.0- Paroxysmal atrial fibrillation
 - 148.1- Persistent atrial fibrillation
 - 148.2- Chronic atrial fibrillation
 - 148.91- Unspecified atrial fibrillation
- Place of service code: 21 (inpatient hospital)
- Secondary diagnosis code Z00.6
- Modifier Q0
- Clinical trial number (NCT02699957) in item 23 of CMS-1500 form or electronic equivalent

Co-surgeon Billing: Left atrial appendage closure may be billed by two physicians by appending the -62 modifier to 33340 (eg: 33340-62).² This modifier has a two specialty requirement meaning that each physician billing the procedure must be of a different specialty. Documentation for using this modifier is not needed as long as this requirement is met. For example, an EP and IC can perform the procedure together and bill for their part of the implantation. Each physician will bill 33340-62 and each be paid 62.5% of Medicare's allowable.³ Thus, the total physician payment from Medicare would be at 125% of what would normally be paid if one surgeon were performing the procedure.

¹ <https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/downloads/MM9638.pdf>

² <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFS-Relative-Value-Files-Items/RVU17B.html?DLPage=1&DLEntries=10&DLSort=0&DLSortDir=descending>

³ <https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/downloads/SE1322.pdf>

Echocardiography

Transesophageal echocardiography (TEE) plays a critical role in visualization and assisting with appropriate candidacy for the WATCHMAN Device. Based on our Directions for Use, the WATCHMAN procedure involves use of TEE imaging as follows:

- Baseline TEE: Performed prior to the implant procedure to determine if the patient is a suitable candidate for the WATCHMAN Device. (CPT code: 93312)
- Intraoperative TEE: Performed during the WATCHMAN implant procedure and provides guided imaging to facilitate device placement (CPT code: 93355).
- Follow up TEE: Performed at 45 days and 12 months after the WATCHMAN implant to ensure appropriate endothelialization/healing of the left atrial appendage (LAA). Based on physician assessment, additional follow up TEE may be recommended. (CPT code: 93312).

The baseline and follow up TEE to support the WATCHMAN procedure may be reported with the following code as appropriate:

93312: Echocardiography, transesophageal, real-time with image documentation (2D) (with or without M-mode recording); including probe placement, image acquisition, interpretation and report

The code 93355 applies to intraoperative TEE's done during WATCHMAN and other structural heart interventional procedures. Code, 93355 includes real-time guidance, image acquisition, documentation and interpretation during transcatheter intracardiac procedures. The work value for this code is 4.66 with total RVUs of 6.47 for CY2017.

NOTE: Code 93355 is reported once per intervention and only by an individual who is not performing the interventional procedure (i.e., WATCHMAN implant). A corrective coding initiative (CCI) edit exists with the code pairs 33340 and 93355 which indicate that these code pairs should not be reported together.

The complete descriptor for code 93355 is:

93355: Echocardiography, transesophageal (TEE) for guidance of a transcatheter intracardiac or great vessel(s) structural intervention(s) (e.g., TAVR, transcatheter pulmonary valve replacement, mitral valve repair, paravalvular regurgitation repair, left atrial appendage occlusion/closure, ventricular septal defect closure) (peri-and intra-procedural), real-time image acquisition and documentation, guidance with quantitative measurements, probe manipulation, interpretation, and report, including diagnostic transesophageal echocardiography and, when performed, administration of ultrasound contrast, Doppler, color flow, and 3D.

Physician Coverage

CMS established a national coverage determination (NCD) for percutaneous LAAC therapy. The NCD defines specific criteria for physicians and hospitals performing LAAC therapy with an effective date of February 8, 2016. As a result, codes used to report the WATCHMAN™ procedure should no longer be treated as investigational and experimental technology.. Medicare administrative contractors (MACs) and Medicare Advantage plans must follow the national coverage policy established by the NCD. We expect WATCHMAN implants performed prior to the NCD effective date would be adjudicated by the local contractors based on their policies in place at the time of the WATCHMAN implant.

Private and commercial payers may choose to follow the NCD guidance or establish their own policies for LAAC therapy. Therefore, it is important to understand payer policies and seek prior authorizations with private payers to establish the medical necessity for WATCHMAN in advance of performing the implant. Resources to support this process are provided in the Payer Communications and Prior Authorization sections of this document and on the website www.bostonscientific.com.

Physician Payment*

The code used by physicians to report left atrial appendage closure with implant procedures is 33340. This code has a total RVU value of 23.22 with a work RVU of 14.0, This RVU value correlates to a national average physician payment of approximately \$833.

*National Average Medicare physician payment rates calculated using the 2017 conversion factor of \$35.7751

Hospital Coding

Inpatient hospital procedures will be reported using ICD10 procedure codes (ICD-10-PCS). The appropriate ICD10 procedure code for reporting the WATCHMAN implant is 02L73DK:

ICD-10 Procedure code	Procedure Description
02L73DK	Occlusion of left atrial appendage with intraluminal device, percutaneous approach

Medicare has determined that the WATCHMAN LAAC procedure must be performed in the inpatient hospital site of service. The WATCHMAN procedure is not an approved procedure in the outpatient hospital setting. The Medicare inpatient-only list of codes is found in [Addendum E](#).

Medicare's "Inpatient-Only" list at 42 C.F.R. § 419.22(n) defines services that support an inpatient admission and Part A payment as appropriate, regardless of the expected length of stay. Therefore, Medicare's two midnight rule does not apply to "In-patient Only" procedures. Additional information can be found by clicking this [link](#).

Some private payers may allow the WATCHMAN procedure to be performed in the hospital outpatient setting, but coverage and payment will vary so it is important to verify and confirm with your payer.

Based on CMS billing instructions, hospital claims will need to have the following items to support the NCD for percutaneous LAAC procedures.⁴ For dates of service on or after February 8, 2016 (the NCD effective date), hospital claims will be paid only when billed with the following codes:

- ICD-10 procedure code 02L73DK
- Primary ICD-10 diagnosis code (one of the following):
 - I48.0- Paroxysmal atrial fibrillation
 - I48.1- Persistent atrial fibrillation
 - I48.2- Chronic atrial fibrillation
 - I48.91- Unspecified atrial fibrillation
- Secondary diagnosis code Z00.6
- Condition code 30 (Qualifying clinical trial)
- Value code D4: Clinical trial number (NCT02699957)

⁴ <https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/downloads/MM9638.pdf>

C-codes

The WATCHMAN procedure is designated by Medicare as an inpatient only procedure. Therefore, no C- code is assigned to the WATCHMAN Device. C-codes are reported for device-intensive procedures performed in the outpatient hospital site of service.

Hospital Payment

Inpatient services are assigned to Medicare Severity Diagnosis Related Groups (MS-DRGs) for payment. Based on the inpatient ICD-10-PCS code (02L73DK) and the most typical diagnosis of atrial fibrillation, WATCHMAN procedures will likely map to MS-DRG 273 or 274. This assignment is representative of percutaneous intracardiac procedures such as WATCHMAN LAAC implants, cardiac surgical ablations, and transcatheter mitral valve replacement procedures.

MS-DRG	MS-DRG Description	FY2017 National Average Base Payment**
MS-DRG 273	Percutaneous Intracardiac Procedures with MCC	\$ 21,495
MS-DRG 274	Percutaneous Intracardiac Procedures without MCC	\$ 15,089

** Centers for Medicare and Medicaid Services. Medicare Program: [FY20167 Hospital Inpatient Prospective Payment System, Final Rule](#); August 2, 2016

Hospital Coverage

As of effective date February 8, 2016, CMS established coverage for the WATCHMAN LAAC procedure under the NCD for percutaneous LAAC therapy when seven conditions are met. Upon implementation of CMS's program instructions, the NCD creates uniform and consistent coverage for appropriate Medicare beneficiaries.. Medicare Advantage Plans must also follow the NCD. (Please refer to the NCD coverage section on page 3.) WATCHMAN implants performed prior to the NCD effective date will be adjudicated by the local contractors based on their policies in place at the time of the procedure.

CMS is covering LAAC under coverage with evidence development (CED) which requires data collection to better monitor the long-term efficacy of this therapy on Medicare beneficiaries. As part of CED, hospitals must participate in the national registry for LAAC. CMS has certified the National Cardiovascular Data Registry (NCDR®) LAAO Registry™ (Left Atrial Appendage Occlusion) as the official registry for the LAAC NCD. Please contact NCDR about enrollment and questions on data collection by going to the [NCDR website](#), contacting them at ncdr@acc.org or by calling 1-800-257-4737.

Private and commercial payers may choose to follow the NCD guidance or establish their own policies for LAAC therapy. Therefore, it is important to seek prior authorizations with private payers to establish the medical necessity for WATCHMAN in advance of performing the implant. Resources to support this process are provided in the Payer Communications and Prior Authorization sections of this document or click on the website: www.bostonscientific.com.

Payer Communications

FDA Approval

The WATCHMAN LAAC Device has received FDA approval so it should not be treated as an investigational device. Please go to www.bostonscientific.com to access the FDA approval letter to include in your prior authorization and appeals requests.

The 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-VASc⁵ 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.

WATCHMAN™ LAAC Procedure

Effective February 8, 2016, WATCHMAN procedures should no longer be treated as investigational and experimental by MACs and Medicare Advantage Plans if patients satisfy all conditions for coverage as defined in the NCD. It is important to work with MACs and commercial payers prior to the effective date of the NCD to establish medical necessity for the procedure via the appeals.

Private payer, coverage will be based on their policies for LAAC procedures. It is important that physicians and hospital providers check existing policies in advance of performing WATCHMAN implants. In addition, physician and hospital providers should always seek prior authorization for individual coverage consideration of WATCHMAN based on the patients' clinical condition. Prior authorization and peer-to-peer reviews are recommended tools for assisting with patient access in light of private payer non-coverage policies that may exist in lieu of the NCD. Please refer to the Prior-Authorization section to assist with best practices in securing approval for WATCHMAN LAAC procedures.

⁵ January CT, Wann LS, Alpert JS, et. al., 2014 AHA/ACC/HRS Guideline for the Management of Patients With Atrial Fibrillation A Report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines and the Heart Rhythm Society, Circulation, 2014; 130: e199-e267.

Prior Authorization Resources

Traditional Medicare

Medicare fee-for-service does not offer prior authorizations for any services including the WATCHMAN LAAC procedure.

Medicare Advantage and Other Private Payers

Prior authorization is a process established by commercial insurance plans that allows a physician to submit a treatment plan prior to surgery. The insurer reviews the treatment plan as well as the patient's insurance benefits and medical policies to determine if the treatment is covered and the applicable patient responsibility (e.g., coinsurance and/or copay, deductibles, and out-of-pocket amounts). As prior authorization processes vary by insurer, it is important to contact insurance plans and follow their specific requirements.

Prior authorization requests typically include the following elements:

- Patient information — name, date of birth, policy number
- Details of the patient's medical history
- Description of the patient's current condition and treatment plan
- Letter of medical necessity (LOMN) documenting the patient's medical need
- Proposed procedure(s), medical device implanted and rationale for treatment
- Proposed location of service and dates planned
- Summary of the clinical evidence supporting the treatment plan including comorbidities and copies of published literature supporting the safety and effectiveness. Peer review literature regarding the WATCHMAN include:
 - Holmes, DR, Reddy VY, Doshi, SK et al. Percutaneous closure of the left atrial appendage versus warfarin therapy for prevention of stroke in patients with atrial fibrillation: a randomized non-inferiority trial (PROTECT AF). *Lancet*. 2009; 374:534-42.
 - Reddy, VY, Doshi, SK, Sievert, H et al. Percutaneous left atrial appendage closure for stroke prophylaxis in patients with atrial fibrillation: 2.3-year follow-up of the PROTECT AF (WATCHMAN left atrial appendage system for embolic protection in patients with atrial fibrillation) Trial. *Circulation*. 2013; 127: 720-729.
 - Holmes DR, Kar S, Price M, Whisenant B, Sievert H, Doshi S, Huber K, Reddy V. Prospective randomized evaluation of the Watchman left atrial appendage Device in patients with atrial fibrillation versus long-term warfarin therapy; the PREVAIL trial. *Journal of the American College of Cardiology*, Vol. 4, No. 1, 2014, 1-11.
 - Reddy VY, Sievert H, Halperin J, et al. Percutaneous Left Atrial Appendage Closure vs Warfarin for Atrial Fibrillation: A randomized clinical trial. *JAMA*. 2014;312(19): 1988-1998.
 - Holmes DR, Jr., Doshi SK, Kar S, et al. Left Atrial Appendage Closure as an Alternative to Warfarin for Stroke Prevention in Atrial Fibrillation: A Patient- Level Meta-Analysis. *J Am Coll Cardiol*. 2015;65(24):2614-2623. doi:10.1016/j.jacc.2015.04.025.
- Description of the technology and rationale for its use
- Copy of the FDA approval letter (available through your Boston Scientific Sales Representative or by calling 1-800-CARDIAC, and ask for the reimbursement support line)

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

Appealing Denials

MACs, commercial and private payers have documented appeals processes for reconsidering denials. Since Medicare does not perform prior authorizations, providers would proceed with performing the procedure (based on the patient meeting the coverage indications as outlined in the NCD), submit the claim to the MAC, and then wait to receive a payment or denial. If the MAC denies the claim, Medicare has a defined appeals process with up to five levels of appeals. Additional information and an overview of this process are found by clicking [here](#). The first level of Medicare appeal is known as “Redetermination” allows providers to appeal the denial within 120 days from the date of the initial claim denial. Medicare provides a specific form ([Form CMS-20027](#)) to standardize the information needed to request initial redeterminations. If you should receive a denial from the Medicare contractor, you have the right to appeal the claim by referencing the NCD and indicating how your patient meets the coverage criteria.

In lieu of the NCD for LAAC therapy, many private payers have decided to cover WATCHMAN, but some plans may continue with existing non-coverage policies. Therefore, we encourage providers to continue to seek prior authorizations with private payers to establish medical necessity in advance of performing the procedure. Should you receive denials, appeals information for the private payers is often found in the plan’s provider manual and/or website or by contacting the insurer directly. If you need to appeal a prior authorization denial, physician providers should request a peer-to-peer review with a like specialty (i.e. Electrophysiology or Interventional Cardiology) to best communicate the WATCHMAN™ LAA closure procedure and patient treatment pathway.

During the peer to peer review, focus on the benefits of the WATCHMAN LAAC technology and the medical necessity based upon the individual patient’s symptoms, diagnosis and comorbidities. Clinicians may also request a third party peer-to-peer review of the claim requesting a board-certified Electrophysiologist or cardiologist who understands the therapy.

Appeal letters typically include the following elements for both Medicare and private payers:

- Provide the rationale for filing an appeal (denial of coverage, medical necessity, etc.)
- Date of denial/denial letter
- Reference the denial reason and associated denial code, if applicable
- Detail the patient’s diagnosis and course of treatment including adverse outcomes or lack of improvement from prior therapies.
- Describe the procedure in detail
- Describe any medical device and its benefits as they relate to the patient’s condition. Emphasize the advantages of the medical device as compared to another medical device or approach
- State the rationale and benefits of the technology and how its use can be expected to produce a superior clinical outcome for the patient
- Discuss personal experiences and outcomes of surgical cases using the medical device
- Reference peer review literature to support the clinical determination regarding medical necessity. Recent peer review literature regarding the WATCHMAN device include:

- Holmes, DR, Reddy VY, Doshi, SK et al. Percutaneous closure of the left atrial appendage versus warfarin therapy for prevention of stroke in patients with atrial fibrillation: a randomized non-inferiority trial (PROTECT AF). *Lancet*. 2009; 374:534-42.
 - Reddy, VY, Doshi, SK, Sievert, H et al. Percutaneous left atrial appendage closure for stroke prophylaxis in patients with atrial fibrillation: 2.3-year follow-up of the PROTECT AF (WATCHMAN left atrial appendage system for embolic protection in patients with atrial fibrillation) Trial. *Circulation*. 2013; 127: 720-729.
 - Holmes DR, Kar S, Price M, Whisenant B, Sievert H, Doshi S, Huber K, Reddy V. Prospective randomized evaluation of the Watchman left atrial appendage Device in patients with atrial fibrillation versus long-term warfarin therapy; the PREVAIL trial. *Journal of the American College of Cardiology*, Vol. 4, No. 1, 2014, 1-11.
 - Reddy VY, Sievert H, Halperin J, et al. Percutaneous Left Atrial Appendage Closure vs Warfarin for Atrial Fibrillation: A randomized clinical trial. *JAMA*. 2014;312(19): 1988-1998.
 - Holmes DR, Jr., Doshi SK, Kar S, et al. Left Atrial Appendage Closure as an Alternative to Warfarin for Stroke Prevention in Atrial Fibrillation: A Patient-Level Meta-Analysis. *J Am Coll Cardiol*. 2015;65(24):2614-2623. doi:10.1016/j.jacc.2015.04.025.
- Provide a contact name and phone number as well as the willingness to answer questions or provide additional information
 - Request a specific timeframe for a response

Please go to the WATCHMAN Device website: www.bostonscientific.com to access a sample appeals template that you can customize specific to the medical appropriateness of WATCHMAN Device for your patients.

Coding & Reimbursement Support

Boston Scientific is dedicated to providing physicians, allied health professionals and hospitals with world-class programs and services to help advance the standard of patient care and appropriate access to life-enhancing technologies.

Call **1.800.CARDIAC (227.3422)** and ask for “WATCHMAN Reimbursement.”

All WATCHMAN reimbursement resources are easily accessed at www.bostonscientific.com.

Important Information

Health economics 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 provided 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. Boston Scientific does not promote the use of its products outside their FDA-approved label.

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.

References

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

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