WATCHMAN REIMBURSEMENT GUIDE

This comprehensive guide provides an overview of the coding, coverage and payment landscape for the WATCHMAN system.

For questions regarding WATCHMAN™ reimbursement, please contact:

Email: WATCHMAN.Reimbursement@bsci.com

Phone (toll free): (877) 786-1050

Please go to www.watchmandownloadcenter.com for additional resources.



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.

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IMPORTANT INFORMATION

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

CPT Copyright 2019 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.

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.



CODING SUMMARY

	Hospital Inpatient	Physician
Coding	ICD-10-PCS Procedure Code 02L73DK	CPT Code 33340
Payment	MS-DRG 273 or MS-DRG 274	14 Work RVUs 22.93 Total RVUs
Diagnosis Codes	ICD-10-CM Diagnosis Codes 148.91 Unspecified Atrial Fibrillation 148.20 Chronic Atrial Fibrillation, Unspecified* 148.21 Permanent Atrial Fibrillation 148.0 Paroxysmal Atrial Fibrillation 148.11 Longstanding Persistent Atrial Fibrillation 148.19 Other Persistent Atrial Fibrillation	
Coverage	Original Medicare – CMS National Coverage Determination (NCD CED 20.34) establishes uniform coverage criteria¹ Medicare Advantage – Medicare Advantage plans must cover all the services that Original Medicare covers. The NCD CED 20.34 coverage criteria for Original Medicare also provides coverage to Medicare Advantage Patients² Private Payers – Coverage dependent on individual payer policy	

^{*}The unspecified code is **NOT COVERED** under the NCD for LAAC. LAAC claims reported with this diagnosis code will be denied. Some private payers have included this ICD-10-CM code in their coverage policy



¹ https://www.cms.gov/medicare-coverage-database/details/nca-decision-memo.aspx?NCAId=281

² https://www.medicare.gov/what-medicare-covers/what-medicare-health-plans-cover/medicareadvantage-plans-cover-all-medicare-services

ICD-10-CM DIAGNOSIS CODES

FY 2020 ICD-10-CM Atrial Fibrillation Diagnosis **Coding Update**

Updates to ICD-10-CM diagnosis codes related to Atrial Fibrillation were announced in the FY 2020 IPPS Final Rule and are effective as of October 1, 2019. Updates are described in CMS 2382, change request #11491.

Use of the new codes is required to facilitate claims processing for services associated with an AF diagnosis, including Left Atrial Appendage Closure (LAAC).

Previous Code(s) Assignment	Current Code Assignment
End Date September 30, 2019	FY 2020 – Effective October 1, 2019
I48.91 Unspecified Atrial Fibrillation I48.2 Chronic Atrial Fibrillation I48.0 Paroxysmal Atrial Fibrillation I48.1 Persistent Atrial Fibrillation	 I48.91 Unspecified Atrial Fibrillation I48.20 Chronic Atrial Fibrillation, Unspecified* I48.21 Permanent Atrial Fibrillation I48.0 Paroxysmal Atrial Fibrillation I48.11 Longstanding Persistent Atrial Fibrillation I48.19 Other Persistent Atrial Fibrillation

^{*}The unspecified code is NOT COVERED under the NCD for LAAC. LAAC claims reported with this diagnosis code will be denied.



HOSPITAL REIMBURSEMENT

Medicare classifies WATCHMAN LAAC procedures as Inpatient-only.

The "Two-Midnight Rule" is not applicable for procedures restricted to the Inpatient Only (IPO) list.

ICD-10-PCS	MS-DRG Description		
02L73DK	Occlusion of left atrial appendage with intraluminal device, percutaneous approach.		
MS-DRG	MS-DRG Description FY 2020 National Average Payment*		
MS-DRG 273	Percutaneous Intracardiac Procedures with MCC	\$23,240	
MS-DRG 274	Percutaneous Intracardiac Procedures without MCC	\$19,792	

^{*}Centers for Medicare and Medicaid Services. Medicare Program: FY2020 Hospital Inpatient Prospective Payment System, Final Rule; August 2, 2019.

https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Internet-Only-Manuals-IOMs-number of the control of the controItems/CMS018912.html

Major Complication or Comorbidity (MCC) Examples

- End Stage Renal Disease (N18.6)
- Acute Respiratory Failure (J96.00, J96.01, J95.821)
- Acute on Chronic Heart Failure (I50.23, I50.33, I50.43)
- Acute Diastolic Heart Failure (I50.31)



HOSPITAL REIMBURSEMENT

Continued

Transesophageal Echocardiogram (TEE) — Baseline and Follow-Up

Code	Description	APC	CY 2020 National Average Payment*
93312	Echocardiography, transesophageal, real-time with image documentation (2D) (with or without M-mode recording); including probe placement, image acquisition, interpretation and report.	5524	\$482

^{*}Commercial payment will vary and will be at discretion of the payer.

Computed Tomography (CT) — Baseline and Follow-Up

Code	Description	APC	CY 2020 National Average Payment*
75572	Computed tomography, heart, with contrast structure and morphology (including 3D image postprocessing, assessment of cardiac function, and evaluation of venous structures, if performed).		
75574	Computed tomography, heart, coronary arteries and bypass grafts (when present), with contrast material, including 3D image postprocessing (including evaluation of cardiac structure and morphology, assessment of cardiac function, and evaluation of venous structures, if performed).	5571	\$182

^{*}Commercial payment will vary and will be at discretion of the payer.



HOSPITAL REIMBURSEMENT

Continued

Transesophageal Echocardiogram (TEE) — Intraoperative

Code	Description	APC	CY 2020 National Average Payment*
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.	Not Applicable – N Status Indicator	Bundled Service

^{*}Commercial payment will vary and will be at discretion of the payer.



WATCHMAN LAAC Procedure

Code	Description	RVU	CY 2020 National Average Payment*
33340	Percutaneous transcatheter closure of the left atrial appendage with implant, including fluoroscopy, transseptal puncture, catheter placement(s), left atrial angiography, left atrial appendage angiography, radiological supervision and interpretation.	14.00 work RVUs 22.93 Total RVUs	\$829

^{*}Commercial payment will vary and will be at discretion of the payer.

Same Physician Performing Implant and Intraoperative TEE

CPT 33340 (WATCHMAN) and 93355 (Intraoperative TEE) can not be billed by the physician billing 33340.

1 Medicare – National Correct Coding Policy Manual, Physician Version 23.0/Policy Narratives (1/1/2017): Chapter I General Correct Coding Policies, Excerpt – Section E.



Continued

Co-Surgeon Billing

CPT Code + Modifier	Description	
33340-62	Left atrial appendage closure can be billed by two surgeons by appending the -62 modifier to 33340 (eg. 33340-62).	

- If two surgeons (each of a different specialty) are required to perform a specific procedure, each surgeon bills for the procedure with a modifier of "-62"
- Each operator is required to submit their own post-operative note and must report 33340-62
- The fee schedule amount applicable to the payment for each co-surgeon is 62.5 percent of the global surgery fee amount

Transesophageal Echocardiogram (TEE) — Baseline and Follow-Up

Code	Description	RVU	CY 2020 National Average Payment**
93312	Echocardiography, transesophageal, real-time with image documentation (2D) (with or without M-mode recording); including probe placement, image acquisition, interpretation and report.	2.30 work RVUs 6.96 Total NonFacility RVUs 3.12 Total Facility RVUs (-26)	Global \$251 Professional \$113

^{*}Commercial payment will vary and will be at discretion of the payer.



^{**}Global includes professional and technical services. Professional only includes services reported with -26 modifier.

Continued

Computed Tomography (CT) — Baseline and Follow-Up

Code	Description	RVU	CY 2020 National Average Payment*
75572	Computed tomography, heart, with contrast material, for evaluation of cardiac structure and morphology (including 3D image postprocessing, assessment of cardiac function, and evaluation of venuous structures, if performed).	1.75 work RVUs 7.01 NonFacility Total RVUs 2.46 Facility Total RVUs (-26)	Global \$271 Professional \$89
75574	Computed tomographic angiography, heart, coronary arteries and bypass grafts (when present), with contrast material, including 3D image postprocessing (including evaluation of cardiac structure and morphology, assessment of cardiac function, and evaluation of venous structures, if performed)	2.40 work RVUs 10.13 NonFacility Total RVUs 3.35 Facility Total RVUs (-26)	Global \$366 Professional \$121

^{**}Commercial payment will vary and will be at discretion of the payer.

^{**}Global includes professional and technical services. Professional only includes services reported with -26 modifier.

Continued

Transesophageal Echocardiogram (TEE) — Intraoperative

Code	Description	RVU	CY 2020 National Average Payment**
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 intraprocedural), 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.	4.66 work RVUs 6.58 Total RVUs	\$237

^{*}Commercial payment will vary and will be at discretion of the payer.

Same Physician Performing Anesthesia and Intraoperative TEE

CPT 01926 (Anesthesia) and 93355 (Intraoperative TEE) can not be billed by the physician billing 01926.

1 Medicare – National Correct Coding Policy Manual, Physician Version 23.0/Policy Narratives (1/1/2017): Chapter I General Correct Coding Policies, Excerpt – Section E.



^{**}Code 93355 RVU for global payment only, no separate professional component applies.

PROFESSIONAL CLAIM BILLING **INSTRUCTIONS**

- 1 CPT Code 33340 Percutaneous transcatheter closure of the left atrial appendage with implant, including fluoroscopy transseptal puncture, catheter placement(s), left atrial angiography, left atrial appendage angiography, radiological supervision and interpretation
- 2 Principal ICD-10-CM Diagnosis Code (one of the following):
 - I48.0 Paroxysmal atrial fibrillation
 - I48.11 Longstanding persistent atrial fibrillation (NEW Effective October 1, 2019)
 - 148.19 Other persistent atrial fibrillation (NEW Effective October 1, 2019)
 - I48.20 Chronic atrial fibrillation, unspecified* (NEW Effective October 1, 2019)
 - I48.21– Permanent atrial fibrillation (NEW Effective October 1, 2019)
 - I48.91 Unspecified atrial fibrillation
- 3 Place of Service Code of 21 Inpatient hospital
- 4. Secondary Diagnosis Code Z00.6 Encounter for exam of participant in clinical research program to indicate a patient is participating in LAAO Registry
- 5. Modifier Q0 Indicating the procedure is an investigational clinical service provided in an approved clinical research study
- 6. Clinical Trial Number CT 02699957

The 8-digit clinical trial registry number preceded by the alpha characteristic "CT", is placed in field/item 19 of the CMS 1500 claim form or in the electronic claim equivalent 837p in Loop 2300 REF02(REF01=P4)(this is actually field/item 23).



^{*}The unspecified code is NOT COVERED under the CMS NCD for LAAC. Some private payers have included this ICD-10 code in their coverage policy

CMS 1500 Claim Example for WATCHMANTM LAAO Device

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INSTITUTIONAL HOSPITAL CLAIMS BILLING INSTRUCTIONS

- 1 ICD-10-PCS Procedure Code 02L73DK Occlusion of Left Atrial Appendage with Intraluminal Device, Percutaneous Approach
- 2 Principal ICD-10-CM Diagnosis Code of one of the following:
 - I48.0 Paroxysmal atrial fibrillation
 - I48.11 Longstanding persistent atrial fibrillation (NEW Effective October 1, 2019)
 - I48.19 Other persistent atrial fibrillation (NEW Effective October 1, 2019)
 - I48.20 Chronic atrial fibrillation, unspecified* (NEW Effective October 1, 2019)
 - I48.21 Permanent atrial fibrillation (NEW Effective October 1, 2019)
 - I48.91 Unspecified atrial fibrillation
- 3 Secondary Diagnosis Code Z00.6 Encounter for exam of participant in clinical research program to indicate a patient is participating in LAAO Registry
- 4. Condition Code 30 Qualifying Clinical Trial
- 5. Value Code D4 Clinical Trial Number (NCT 02699957) is listed on the CMS website: clinicaltrials.gov

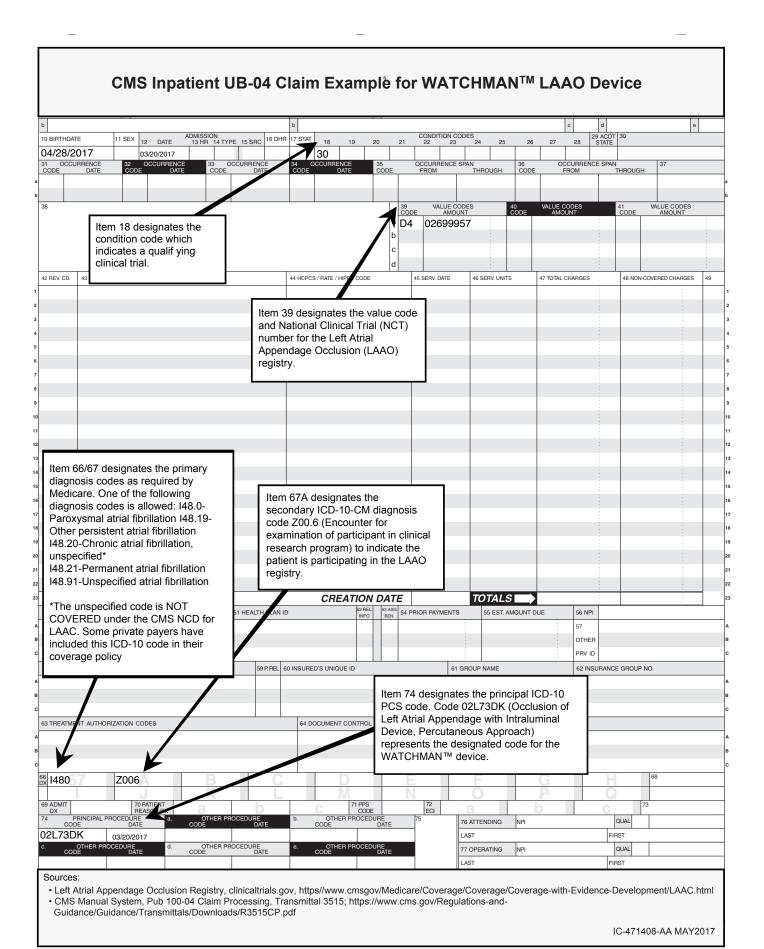
https://www.cms.gov/Medicare/Coverage/Coverage-with-Evidence-Development/LAAC

https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/downloads/R3515CP.pdf

https://www.cms.gov/Medicare/Coding/ICD10/2020-ICD-10-CM.html



^{*}The unspecified code is NOT COVERED under the CMS NCD for LAAC. Some private payers have included this ICD-10-CM code in their coverage policy



INSTITUTIONAL HOSPITAL CLAIMS BILLING INSTRUCTIONS

Continued

Device C-Code

The WATCHMAN device is classified by Medicare as an "Inpatient Only" procedure therefore no HCPCS device category C-code exists for WATCHMAN

- A hospital may assign its own internal charge code, associated with an appropriate revenue code, to record the cost of the device.
- If a device category C-code is required by the hospital charging system, please review the web link below for the CMS approved list as of January 1, 2019.

Using the camera on your phone, scan the QR code and visit the sites.



https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ HospitalOutpatientPPS/Downloads/Complet-list-DeviceCats-OPPS.pdf



DISCONTINUED OR ABORTED PROCEDURE FOR IN-PATIENT SERVICES

Discontinued or Aborted Procedures vary based on patient case details and physician documentation. The following scenario represents only one type of case. Consult AHA Coding Clinic and Official Coding Guidelines in the event of other clinical scenarios.

Scenario: During same operative episode the WATCHMAN device was inserted, determined by the physician to be inadequate and the device was removed.

ICD-10 PCS 02H73DZ Insertion of Intraluminal Device into Left Atrium, Percutaneous Approach

• Root Operation Definition: Putting in a nonbiological appliance that monitors, assists, performs, or prevents a physiological function but does not physically take the place of a body part.

AND

ICD-10 PCS 02PA3DZ Removal of Intraluminal Device from Heart, Percutaneous

• Root Operation Definition: Taking out or off a device from a body part.

2020 ICD-10 PCS Official Guidelines for Coding and Reporting (page 76), Guideline B6.1a.

American Hospital Association (AHA) Coding Clinic for ICD-10-CM/PCS, Fourth Quarter 2017: Page 104; Fourth Quarter ICD-10 2018 Page: 94



DISCONTINUED OR ABORTED PHYSICIAN SERVICES

- CPT Code 33340
- May use modifier 53 for a Discontinued Procedure
- The modifier is used to report services or procedures when the service/procedure is discontinued after anesthesia is administered to the patient. Submit the length/amount of procedure completed and reason for discontinued services.
- The physician can only code for what was accomplished in the procedure (e.g., groin access; or, transseptal puncture and imaging; or, inspection, insertion and removal)

2019 ICD-10 PCS Official Guidelines for Coding and Reporting (page 76), Guideline B6.1a. American Hospital Association (AHA) Coding Clinic for ICD-10-CM/PCS, Fourth Quarter 2017: Page 104; Fourth Quarter ICD-10 2018 Page: 94



CONCOMITANT PROCEDURE BILLING FOR HOSPITAL INPATIENT SERVICES

MS-DRG Hierarchy

When a WATCHMAN device is performed during the same hospital admission as another procedure, only one MS-DRG is assigned for payment.

- Since a patient can have multiple procedures related to their principal diagnosis, and a patient can be assigned to only MS-DRG, patients with multiple procedures are assigned to the surgical class highest in the CMS defined hierarchy.
- Each case is specific to clinical circumstances of the admission.
- The assignment of the principal diagnosis and procedure are critical for accurate MS-DRG assignment.
- Sequence procedure performed for definitive treatment most related to principal diagnosis as principal procedure.

Inpatient Readmissions

When an inpatient hospital WATCHMAN device admission follows a previous inpatient admission for a related or unrelated procedure, readmission policies may apply. A quality review may be triggered and warrant a case review to evaluate combining the inpatient admissions. Each case is specific to clinical circumstances for each admission.

https://www.cms.gov/icd10m/version37-fullcode cms/fullcode_cms/Design_and_development_of_the_ Diagnosis_Related_Group_(DRGs).pdf

https://www.cms.gov/Medicare/Coding/ICD10/Downloads/2020-ICD-10-PCS-Guidelines.pdf



CONCOMITANT PROCEDURE BILLING FOR PHYSICIAN SERVICES

When a WATCHMAN device is performed during the same operative episode as another procedure, the Medicare Multiple Discounting policy applies.

- Multiple Procedure Discount payment adjustment rule for multiple procedures applies to the service. The WATCHMAN procedure is assigned a '2' which indicates that standard payment adjustment rules for multiple procedures apply.
 - 100 percent of the fee schedule amount for the highest valued procedure; and
 - 50 percent of the fee schedule amount for the second through the fifth highest valued procedures

When a WATCHMAN device is performed on a separate date of service as another procedure, the Medicare Global Days policy applies.

- Global Days time frames that apply to payment for each surgical procedure that describes the applicability of the global concept to the service.
 - WATCHMAN is assigned a 000 global surgery payment indicator. Therefore, only the preoperative and postoperative services related to the procedure for the day of surgery apply. Any services after the day of surgery are separately billable.

https://www.cms.gov/apps/physician-fee-schedule/search/search-criteria.aspx



NATIONAL COVERAGE DETERMINATION (NCD 20.34)

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.

Decision Memo for Percutaneous Left Atrial Appendage (LAA) Closure Therapy:

Using the camera on your phone, scan the QR code and visit the sites.





https://www.cms.gov/medicare-coveragedatabase/details/nca-decision-memo.aspx? NCAId=281

The criteria are highlighted below. Providers are encouraged to read the decision memo in its entirety for additional detail.

The patient must have:

- 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.



NATIONAL COVERAGE DETERMINATION (NCD 20.34)

Continued

Shared Decision Making Resources

Using the camera on your phone, scan the QR code and visit the sites.





https://www.acponline.org/patients_families/products/brochures/afib_booklet.pdf





https://www.nice.org.uk/guidance/cg180/resources/patient-decision-aid-243734797





http://www.acc.org/tools-and-practice-support/quality-programs/anticoagulation-initiative/anticoagulation-shared-decision-making-tool

- A suitability for short-term warfarin but deemed unable to take long term oral anticoagulation following the conclusion of shared decision making
- 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



NATIONAL COVERAGE DETERMINATION (NCD 20.34)

Continued

- The procedure must be performed by an interventional cardiologist(s), electrophysiologist(s) or cardiovascular surgeon(s) that meet the following criteria:
 - Has received training prescribed by the manufacturer on the safe and effective use of the device prior to performing LAAC; and
 - Has performed ≥ 25 interventional cardiac procedures that involve transseptal puncture through an intact septum; and
 - Continues to perform ≥ 25 interventional cardiac procedures that involve transseptal puncture through an intact septum, of which at least 12 are LAAC, over a two-year period.
- The patient is enrolled in, and the MDT and hospital must participate in a prospective, national, audited registry that:
 - 1) consecutively enrolls LAAC patients and
 - 2) tracks the annual outcomes for each patient for a period of at least four years from the time of the LAAC

LAAO 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.

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™.

Using the camera on your phone, scan the QR code and visit the sites.



https://cvquality.acc.org/NCDR-Home/registries/ hospital-registries/laao-registry



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.

Please contact:

WATCHMAN.Reimbursement@bsci.com or 877-786-1050



COMMERCIAL HEALTH 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.

Commercial payers may choose to follow the NCD or establish their own policies for LAAC therapy. It is important review individual coverage policies and to seek prior authorization to establish medical necessity for WATCHMAN in advance of performing the procedure.

Please refer to the WATCHMAN Download Center for the most up-todate list of WATCHMAN private payer coverage and for resources to support prior authorization and appeals.

Using the camera on your phone, scan the QR code and visit the sites.



https://www.watchman.com/hcp/watchman-download-center/healtheconomics-and-reimbursement.html

The Boston Scientific Prior Authorization Team provides assistance in submitting prior authorization requests. Boston Scientific also provides support with appealing denials. The release of patient information is required.

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

Submit completed Boston Scientific prior authorization forms and associated materials to:

Email: PreAuthSupport@bsci.com

Fax: 877-835-2520



COMMERCIAL HEALTH INSURANCE

Continued

WATCHMAN Private Payer Coverage (March 2020)

Health Plan	Primary Service Area	Health Plan	Primary Service Area
AETNA	National	BCBS of Federal Employee Program	National
AmeriHealth	PA, NJ, DC	BCBS of Wyoming	WY
Arkansas Health	AR	Blue Cross ID	ID
Avera	FL, SD, IA, NB	Blue Shield CA	CA
AvMed	FL	Capital Health Plan	FL
BCBS of AL	AL	Capital Bluecross	PA
BCBS of AR	AR	CareFirst BCBS	DC, MD, VA
BCBS Health Advantage	TX	CareSource	ОН
BCBS of AZ	AZ	Centene	National
BCBS of FL	FL	Health Net Federal Services	National
BCBS of IL	IL	Arizona Complete Health	AZ
BCBS of Kansas	KS	Bridgeway Health Solutions	AZ
BCBS of Kansas City	KS	Health Net (CA)	CA
BCBS of Louisiana	LA	California Health and Wellness	CA
BCBS of MA	MA, RI	Sunshine Health	FL
BCBS of MI	MI	Peach State Health	GA
BCBS of MS	MS	Celtic (IL)	IL
BCBS of MT	MT	IlliniCare Health	IL
BCBS of NC	NC	Managed Health Services (IN)	IN
BCBS of NM	NM	Sunflower State Health	KS
BCBS Western NY	NY	Louisiana HealthCare Connections	LA
BCBS of OK	OK	CeltiCare Health	MA
BCBS of RI	RI	Michigan Complete Health	MI
BCBS of TN	TN	Home State Health	MO
BCBS of TX	TX	Magnolia Health	MS
BCBS of SC	SC	Nebraska Total Care	NE
BCBS of Wyoming	WY	New Hampshire Healthy Families	NH



COMMERCIAL HEALTH INSURANCE

Continued

WATCHMAN Private Payer Coverage (March 2020) continued

Health Plan	Primary Service Area	Health Plan	Primary Service Area
SilverSummit	NV	Horizon BCBS	NJ
Buckeye Health	ОН	Humana	National
Trillium Community Health	OR	Independence Blue Cross	PA
Health Net (OR)	OR	Kaiser Permanente	National
Pennsylvania Health & Wellness	PA	LifeWise	OR, WA
Absolute Total Care	SC	Medical Mutual of Ohio	ОН
Superior HealthPlan	TX	Nebraska Blue	NE
Coordinated Care	WA	Optima (Sentara)	VA, OH, NC, WV, FI, MD, PA, SC, GA, CA
Managed Health Services (WI)	WI	Paramount Healthcare	OH, MI
Coordinated Care Health Plan	WA	Premera Blue Cross	WA, AK, OR
Dean Health Plan	WI	Prevera 360	WI
Emblem Health	NY, CT, NJ, FI, PA, NC, MA, SC, GA, CA	Priority Health	MI
Excellus	NY, CT	Regence Health Plan	IA, OH, UT, WA
Fallon	MA, NY, CT, FL, PA, SC	Scott & White Health Plan	TX
Group Health	WA	Summa Health	OH, MD
Harvard Pilgrim	MA, ME, CT, NH, RI, VT, NY	TriCare	National
Hawaii Medical Services Association (HMSA)	HI	Tufts Health Plan	MA, RI, NY
Health Alliance of MI	MI	UPMC	PA
HealthNow (BCBSWNY, BCBSNENY)	NY	Univera	NY
Health New England	MA, CT	Wellmark Blue Cross Blue Shield	IA, SD
Highmark BCBS	DE, PA, WV		

NOTE: Covered lives for Commercial and Federal plans is based on estimates available from Policy Reporter, and excludes those covered by Medicare Advantage plans and/or Medicaid.



ADDITIONAL RESOURCES FOR HEALTH ECONOMICS & MARKET ACCESS SUPPORT

Boston Scientific's Health Economics and Market Access Team is pleased to offer a series of educational webinars to support customers in areas of coding, coverage and market access for their WATCHMAN programs. Please use the following website to register for upcoming webinars:



https://www.watchman.com/en-us-hcp/hema-webinars.html

Using the camera on your phone, scan the QR code and visit the sites.

The webinar topics listed below will be covered each Tuesday on a monthly basis through December 2020:

First Tuesday: Coding and Claims for WATCHMAN procedure 12:00-1:00 pm EST and 3:00-4:00 pm EST

- Understanding WATCHMAN assigned DRGs
- Importance of Documentation
- Review of claims processing for institution and physician

Second Tuesday: National Coverage Determination

12:00-1:00 pm EST and 3:00-4:00 pm EST

- Patient eligibility criteria and shared decision-making
- Facility and Operator Requirements
- National LAAC Registry

Third Tuesday: Resources Supporting Prior Authorization, **Appeals and Beyond**

12:00-1:00 pm EST and 3:00-4:00 pm EST

- Best practices and tools
- Review of Boston Scientific resources
- Commercial payor landscape for Watchman coverage

Any questions regarding these webinars can be directed to ICHEMATEAM@BSCI.COM

