



WATCHMAN FLX Pro

LEFT ATRIAL APPENDAGE CLOSURE DEVICE

Reimbursement Guide

This comprehensive guide provides an overview of the coding, coverage and payment landscape for the WATCHMAN FLX Pro LAAC Device.

For questions regarding WATCHMAN FLX Pro LAAC Device reimbursement, please contact:

Email: WATCHMAN.Reimbursement@bsci.com

Please go to <u>www.watchmandownloadcenter.com</u> for additional resources.

The FDA Approved the WATCHMAN FLX Pro LAAC Device on September 7, 2023.

To access the WATCHMAN FLX Pro LAAC Device approval document, visit <u>the FDA website</u>



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WATCHMAN FLX Pro Device | Brief Summary

CAUTION: Federal law (USA) restricts this device to sale by or on the order of a licensed practitioner. Prior to use, please refer to all applicable "Instructions for Use" for more information on Intended Use/Indications for Use, Contraindications, Warnings, Precautions, Potential Adverse Events, and Operator's Instructions.

Intended Use/Indications for Use

WATCHMAN FLX Pro is intended for percutaneous, transcatheter closure of the left atrial appendage.

Indications for Use

The WATCHMAN FLX Pro 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 CHA₂DS₂-VASc scores and are recommended for anticoagulation therapy.
- Are deemed by their physicians to be suitable for anticoagulation therapy; and
- Have an appropriate rationale to seek a non-pharmacologic alternative to anticoagulation therapy, taking into account the safety and effectiveness of the device compared to anticoagulation therapy.

Contraindications

Do not use the WATCHMAN FLX Pro Device if:

- Intracardiac thrombus is present.
- An atrial septal defect repair or closure device is present.
- A patent foramen ovale repair or closure device is present.
- The LAA anatomy will not accommodate a Closure Device (see Step 7).
- 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 FLX Pro Device is contraindicated.
- Any of the customary contraindications for other percutaneous catheterization procedure (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 anticoagulation therapy, aspirin, or P2Y12 inhibitor.

Warnings

Implantation of the WATCHMAN FLX Pro Device should only be performed by interventional cardiologists and/or electrophysiologists who are proficient in percutaneous procedures, transseptal procedures, the imaging modality utilized and who have completed the WATCHMAN FLX Pro Physician Training program.

- For single use only. Do not reuse, reprocess, or resterilize. Reuse, reprocessing, or
 resterilization may compromise the structural integrity of the Closure Device and/
 or lead to Closure Device failure which, in turn, may result in patient injury, illness,
 or death. Reuse, reprocessing, or resterilization may also create a risk of
 contamination of the Closure Device and/or cause patient infection or crossinfection, including, but not limited to, the transmission of infectious disease(s)
 from one patient to another. Contamination of the Closure Device may lead to
 injury, illness, or death of the patient.
- This device has not been studied in pregnant or breastfeeding women. Careful
 consideration should be given to use of the Closure Device in pregnant and/ or
 breastfeeding women due to the risk of significant exposure to x-rays and the use
 of anticoagulation medication.
- Device selection should be based on accurate LAA measurements obtained using transesophageal or intracardiac echocardiographic imaging guidance in multiple views to avoid improper Closure Device sizing. For TEE recommended in multiple angles [e.g., 0°, 45°, 90°, 135°]; For ICE imaging, visualization of the LAA is recommended with the following anatomical structures: aortic valve (short-axis), mitral valve (long-axis), and pulmonary artery (short-axis), to assess the minimum and maximum diameter of the LAA ostium.
- Do not release (i.e., unscrew) the WATCHMAN FLX Pro Device from the core wire unless all release criteria (Step 15) are satisfied to avoid suboptimal results.
- Potential for Closure Device embolization exists with cardioversion < 30 days following Closure Device implantation; verify Closure Device position after cardioversion during this period.
- If thrombus is observed on the device, anticoagulation therapy is recommended until resolution of thrombus is demonstrated by TEE.
- Appropriate post-procedure drug therapy should be followed. See Post-Procedure Information section for further detail.
- Do not use if the temperature exposure indicator dot on the pouch label is red or missing, indicating Closure Device performance may have been compromised

Precautions

- The safety and effectiveness (and benefit-risk profile) of the WATCHMAN FLX Pro 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, recapturing, and repositioning the Closure Device.
- Use caution when introducing a 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 Closure Device, do not allow the WATCHMAN FLX Pro 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 690 kPa (100 psi).
- Use caution when manipulating the Delivery System. Excessive counterclockwise rotation of the deployment knob or Delivery System hub independent from the rest of the Delivery System can cause premature implant detachment.

MRI Safety Information

A person with the Boston Scientific WATCHMAN FLX Pro Closure Device may be safely scanned under the following conditions. Failure to follow these conditions may result in injury.

Device Name	WATCHMAN FLX Pro Closure Device
Static Magnetic Field Strength (Bo)	1.5 T or 3.0 T
Maximum Spatial Field Gradient	40 T/m (4,000 gauss/cm)
RF Excitation	Circularly Polarized (CP)
RF Transmit Coil Type	There are no Transmit Coil restrictions
RF Receive Coil Type	Any
Operating Mode	Normal Operating Mode
Maximum Whole-Body SAR	2 W/kg (Normal Operating Mode)
Maximum Head SAR	3.2 W/kg (Normal Operating Mode)
Scan Duration	2 W/kg whole-body average SAR for 60 minutes of continuous RF (a sequence or back- to-back series/scan without breaks)
MR Image Artifact	The presence of this implant may produce an image artifact of up to 8 mm.

If information about a specific parameter is not included, there are no conditions associated with that parameter.

Potential Adverse Events

Air embolism, Airway trauma, Allergic reaction to the contrast media, anesthetic, WATCHMAN Implant material, or medication, Altered mental status, Anemia requiring transfusion, Anesthesia risks, 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, Mvocardial erosion, Mvocardial infarction, Nausea, Oral bleeding, Pericardial effusion/ tamponade, Pleural effusion, Prolonged bleeding from a laceration, Pseudoaneurysm, Pulmonary edema, Radiation injury, Renal failure, Respiratory insufficiency/failure, Stroke - Hemorrhagic, Stroke - Ischemic, Surgical removal of the device, TEE complications (e.g., 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.

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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 rendered.

It is also always the provider's responsibility to understand and comply with Medicare national coverage determinations (NCD), Medicare local coverage determinations (LCD), and any other coverage requirements established by relevant payers which can be updated frequently. 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.

This coding information may include codes for procedures for which Boston Scientific currently offers no cleared or approved products. In those instances, such codes have been included solely in the interest of providing users with comprehensive coding information and are not intended to promote the use of any Boston Scientific products for which they are not cleared or approved. The Health Care Provider (HCP) is solely responsible for selecting the site of service and treatment modalities appropriate for the patient based on medically appropriate needs of that patient and the independent medical judgement of the HCP.

CPT Copyright 2024 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.

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CODING summary

	Hospital Inpatient	Physician
Coding	ICD-10-PCS Procedure Code 02L73DK	CPT [®] Code 33340
Payment	MS-DRG 273 or MS-DRG 274 MS-DRG 317 (Concomitant with Cardiac Ablation)	14.00 Work RVUs 22.87 Total RVUs
Diagnosis Codes	ICD-10-CM Diagnosis Codes 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	
Coverage	 Original Medicare – CMS National Coverage Determination (NCD 20.34) establishes uniform coverage criteria¹ Medicare Advantage – Medicare Advantage plans must cover all the services that Original Medicare covers. The NCD 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

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ICD-10-CM diagnosis codes

ICD-10-CM Atrial Fibrillation Diagnosis Coding

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

ICD-10-CM Codes

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 FLX Pro LAAC Device 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



Hospital reimbursement, continued

MS-DRG	MS-DRG Description	FY 2025 National Average Payment*
MS-DRG 273	Percutaneous Intracardiac Procedures with MCC	\$27,906
MS-DRG 274	Percutaneous Intracardiac Procedures without MCC	\$22,273
NEW MS-DRG 317	Concomitant Left Atrial Appendage Closure and Cardiac Ablation	\$44,149

*CMS FY 2025 IPPS Final Rule: CMS-1808-IFC.

https://www.cms.gov/medicare/payment/prospective-payment-systems/acute-inpatient-pps/fy-2025-ipps-final-rule-home-page

Inpatient Readmissions

When an inpatient hospital WATCHMAN FLX Pro LAAC 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/search/cms?keys=design+and+devlopment+of+DRG+groups

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





HOSPITAL REIMBURSEMENT

Continued

Transesophageal Echocardiogram (TEE) – Baseline and Follow-Up

CPT Code	Description	APC	FY 2025 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	\$548

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

Computed Tomography (CT) - Baseline and Follow-Up

CPT Code	Description	APC	FY 2025 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, assess- ment of cardiac function, and evaluation of venous structures, if performed).	5572	\$357

*Cardiac CT procedures moved from APC 5571 to APC 5572 starting in CY2025.



HOSPITAL REIMBURSEMENT

Continued

Transesophageal Echocardiogram (TEE) – Intraoperative

CPT Code	Description	APC	FY 2025 National Average Payment*
93355	Echocariography, 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, para- valvular 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 echocardio- graphy 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.

Intracardiac Echocardiography (ICE) - Intraoperative

CPT Code	Description	APC	FY 2025 National Average Payment*
+93662	Intracardiac echocardiography during therapeutic/diagnostic intervention, including imaging supervision and interpretation (List separately in addition to code for primary procedure).	Not Applicable – N Status Indicator	Bundled Service

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

CMS CY2025 Hospital Outpatient Prospective Payment – Notice of Final Rulemaking (NFRM): CMS-1809-FC. Effective through December 31, 2025.

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Physician reimbursement

WATCHMAN FLX Pro LAAC Device Procedure

CPT Code	Description	RVU	CY 2025 National Average Payment*
33340	Percutaneous transcatheter closure of the left atrial appendage with implant, including fluoroscopy, transseptal puncture, catheter	14.00 Work RVUs	\$740
55540	placement(s), left atrial angiography, left atrial appendage angiography, radiological supervision and interpretation.	22.87 Total RVUs	.pr+0

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

Same Physician Performing Implant and Intraoperative TEE CPT Codes 33340 (WATCHMAN FLX LAAC Device) and 93355 (Intraoperative TEE) can not be billed by the physician cannot be billed by the same physician.

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

FY 2025 СРТ™ National Description **RVU** Code Average Payment* 14.00 Percutaneous transcatheter closure of the left atrial work appendage with implant, including fluoroscopy, **RVUs** 33340 transseptal puncture, catheter placement(s), left atrial 22.87 angiography, left atrial appendage angiography, Total radiological supervision and interpretation **RVUs** Comprehensive electrophysiologic evaluation with transseptal catheterizations, insertion and repositioning \$1,267** of multiple electrode catheters, induction or attempted 17.00 induction of an arrhythmia including left or right atrial work pacing/recording, and intracardiac catheter ablation of 93656 27.72 atrial fibrillation by pulmonary vein isolation, including intracardiac electrophysiologic 3-dimensional mapping, Total **RVUs** intracardiac echocardiography with imaging supervision and interpretation, right ventricular pacing/recording, and His bundle recording, when performed

Concomitant Cardiac Ablation and WATCHMAN FLX LAAC Procedure

*Commercial payment with vary and will be at the discretion of the payer.

**MPPR payment Calculation: \$896.64 + (739.76*.5) = \$1,266.52

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Continued

Medicare Medicare applies a Multiple Procedure Payment Reduction (MPPR) when more than one service is provided to a patient on the same date. The MPPR pays the highest paying procedure at 100% pays the highest paying procedure at 100% and procedures #2-5 at 50%. Commercial payer payment policies will vary.

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 are required to perform a specific portion of the 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% of the global surgery fee amount

CPT Code	Description	RVU	CY 2025 National Average Payment**
93312	Echocardiography, transeso- phageal, real-time with image documentation (2D) (with or without M-mode recording); including probe placement, image acquisition, interpretation and report.	2.30 Work RVUs 6.97 Total Non- Facility RVUs 3.12 Total Facility RVUs (-26)	Global \$225 Professional \$101

Transesophageal Echocardiogram (TEE) – Baseline and Follow-Up

*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.

See page 2 for important information about the uses and limitations of this document.





Continued

Computed Tomography (CT) – Baseline and Follow-Up

CPT Code	Description	RVU	CY 2025 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 6.94 Total Non- Facility RVUs 2.44 Total Facility RVUs (-26)	Global \$224 Professional \$79
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 9.84 Total Non- Facility RVUs 3.37 Total Facility RVUs (-26)	Global \$318 Professional \$109

*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

CPT Code	Description	RVU	CY 2025 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.	4.66 Work RVUs 6.60 Total RVUs	\$213

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

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

Same Physician Performing Anesthesia and Intraoperative TEE

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

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

Intracardiac Echocardiography (ICE) — Intraoperative

CPT Code	Description	RVU	CY 2025 National Average Payment**
+93662	Intracardiac echocardiography during therapeutic/diagnostic intervention, including imaging supervision and interpretation (List separately in addition to code for primary procedure)	1.44 Work RVUs (-26) 2.05 Total RVUs (-26)	\$67

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

**Code 93662 RVU for professional payment only. Professional only includes services reported with -26 modifier.

CMS CY2025 Physician Fee Schedule (PFS) Final Rule: CMS 1807-F, including related PFS addenda. Conversion Factor used in calculations = \$32.3465. Effective through December 31, 2025.





Professional claim billing

- 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
 - I48.19 Other persistent atrial fibrillation
 - I48.20 Chronic atrial fibrillation, unspecified*
 - I48.21– Permanent atrial fibrillation
 - 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



EALTH INSURANCE CLAIM FORM ROVED BY NATIONAL UNIFORM CLAIM COMMITTEE (NUCC) 02/12				
MEDICARE MEDICAID TRICARE CHAMPV		1a. INSURED'S I.D. NUMBER (I	For Program in Item 1)	
(Medicare#) (Medicaid#) (ID#/DoD#) (Member ID ATIENT'S NAME (Last Name, First Name, Middle Initial)	##) (ID#) (ID#) 3. PATIENT'S BIRTH DATE SEX MM DD YY	4. INSURED'S NAME (Last Name, First Name, Mid	de Initial)	
· · · · · · · · · · · · · · · · · · ·		,,	,	
ATIENT'S ADDRESS (No., Street)	6. PATIENT RELATIONSHIP TO INSURED Self Spouse Child Other	7. INSURED'S ADDRESS (No., Street)		
Y STATE	8. RESERVED FOR NUCC USE	CITY	STATE	
CODE TELEPHONE (Include Area Code)		ZIP CODE TELEPHONE (III	nclude Area Code)	
THER INSURED'S NAME (Last Name, First Name, Middle Initial)	10. IS PATIENT'S CONDITION RELATED TO:	11. INSURED'S POLICY GROUP OR FECA NUME	BER	
THER INSURED'S POLICY OR GROUP NUMBER	a. EMPLOYMENT? (Current or Previous)	a. INSURED'S DATE OF BIRTH	SEX	
ESERVED FOR NUCC USE	b. AUTO ACCIDENT? PLACE (State)	b. OTHER CLAIM ID (Designated by NUCC)	F	
Item 21A designates the primary diagnosis	YES NO			
codes as required by Medicare. One of the	. OTHER ACCIDENT?	C. INSURANCE PLAN NAME OR PROGRAM NAM	E	
following diagnosis codes are allowed: I48.0-Paroxysmal atrial fibrillation	Od. CLAIM CODES (Designated by NUCC)	d. IS THERE ANOTHER HEALTH BENEFIT PLAN	?	
I48.11-Longstanding persistent atrial fibrillation			ems 9, 9a, and 9d.	
I48.19-Other persistent atrial fibrillation I48.20-Chronic atrial fibrillation, unspecified*	SIGNING THIS FORM. ease of any medical or other information necessary	 INSURED'S OR AUTHORIZED PERSON'S SIG payment of medical benefits to the undersigned services 		
148.21-Permanent atrial fibrillation	Item 21B designates the	Item 23 designates the		
I48.91-Unspecified atrial fibrillation	secondary ICD-10-CM diagnosis code Z00.6	National Clinical Trial (NCT) number for the Lef		
*The unspecified code is NOT COVERED under the CMS NCD for LAAC. Some private	he private (Encounter for examination of Atrial Appendage Occ			
payers have included this ICD-10 code in their	participant in clinical research	(LAAO) registry.	SERVICES	
coverage policy	program) to indicate the patient is participating in the	FROM		
ADDITIONAL CLAIM INFORMATION (Designated by NUCC)	LAAO registry.	20. OUTSIDE LAB2 \$ CHAF	RGES	
DIAGNO VS OR NATURE OF ILLNESS OR INJURY Relice A-L to servi	ce line below (24E) ICD Ind. 0			
1480 B. 2006 C. L		ORIGINAL REF.	NO.	
F. L G. L	В	23. PRIOR AUTHORIZATION NUMBER		
J. L K. L A. DATE(S) OF SERVICE B. C. D. PROCEI	L. L. DURES, SERVICES, OR SUPPLIES E.	СТ02699957 F. G. H. I.	J.	
	n Unusual Circumstances) DIAGNOSIS	F. G. H. I. DAYS EFSDT OR Family ID. \$ CHARGES UNITS Plan QUAL	RENDERING PROVIDER ID. #	
01 17 01 02 17 21 33340	Q0 A,B	1 NPI		
1 1				
em 24B designates		D designates the HCPCS		
place of service (POS)		r Q0 (Investigational service		
a required by	I [™] FLX to indic	ate the patient is participating		
Aedicare.		AAO registry.		
Sources: iems 21A-21B & 24B-24D) CMSMedicare Claims Proce Matters Number MM9638; Claims Processing Transmitt iem 23-2) Left Atrial Appendage Occlusion <u>Registry, cli</u> <u>AAC.html</u> iem 24D) Official AMA CPT code description 33340 Pe	al 2955 nicaltrials.gov; https//www.cms.gov/Medi	care/Coverage/Coverage-with-Evidence	e-Development/	

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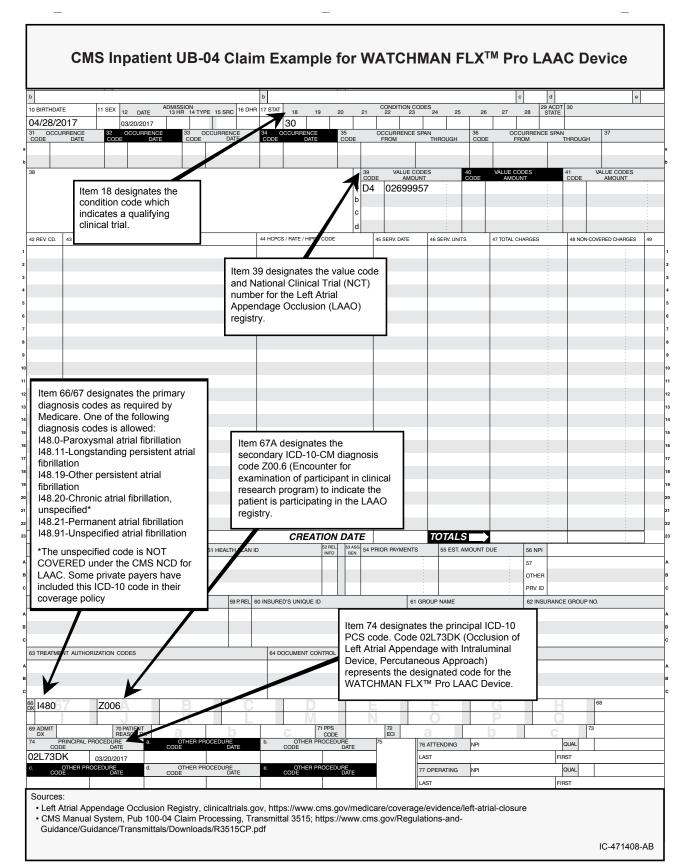
Institutional hospital claims billing

- 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:
 - 148.0 Paroxysmal atrial fibrillation
 - I48.11 Longstanding persistent atrial fibrillation
 - 148.19 Other persistent atrial fibrillation
 - I48.20 Chronic atrial fibrillation, unspecified*
 - 148.21 Permanent atrial fibrillation
 - 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

*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

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/coordination-benefits-recovery/overview/icd-code-lists





See page 2 for important information about the uses and limitations of this document.



INSTITUTIONAL HOSPITAL CLAIMS BILLING

Continued

Device C-Code

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

- 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 October 1, 2024.

https://www.cms.gov/medicare/coding-billing/healthcare-common-procedure-system/coding-questions





Discontinued or aborted procedure billing

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:

The WATCHMAN device is inserted/implanted and removed during the same encounter.

Discontinued or aborted procedures vary based on case details and physician documentation of the procedure. Always consult AHA Coding Clinic and/or other authoritative resources for appropriate coding and billing.

Inpatient Facility 02H73DZ: Insertion of intraluminal device into LA, percutaneous approach,

AND

02PA3DZ: Removal of intraluminal device from heart, percutaneous approach

Outpatient Facility

33340-74: Modifier -74 is used on the CPT[®] code when a procedure is discontinued after it has started, and the patient has received anesthesia.

Professional Services 33340-53

Code assignment is based upon the physician work performed. If, for example, the physician was only able to perform the vascular access, consider reporting code 93452 for the procedure completed.

If the physician performed all the work along with a valid attempt to place the WATCHMAN device, then the planned procedure 33340 with a modifier -53 may be reported.

Modifier -53 is used when a procedure is discontinued for extenuating circumstances such as complications that threaten the patient's safety, including anatomical difficulties.

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





Concomitant procedure billing

Effective for services taking place on or after October 1, 2024, the Centers for Medicare and Medicaid Services (CMS) has established a new hospital mechanism (MS-DRG 317) to appropriately reimburse for costs associated with concomitant ablation to treat atrial fibrillation (AF) and percutaneous left atrial appendage closure (LAAC) using a WATCHMAN[™] device.¹

	Description	FY25 CMS National Rate ¹	
NEW MS-DRG 317	Concomitant Left Atrial Appendage Closure and Cardiac Ablation	\$44,149	

1. CMS FY 2025 IPPS Final Rule: CMS-1808-IFC. Effective through September 30, 2025. See FY2025 CMS Inpatient Reimbursement Update for complete details of the CMS action. https://bostonscientific.showpad.com/share/V5nfwqNvxzliiSqhRwnsl

Hospital Claims Billing

Concomitant cardiac ablation and LAAC

- 1 ICD-10-PCS codes 02583ZF (PFA) or 02583ZZ (thermal ablation) and 02L73DK Use the cardiac ablation code (PFA or thermal) as the principal procedure
- 2 Principal ICD-10-CM diagnosis code of one of the following:
 - 148.0 Paroxysmal atrial fibrillation
 - I48.11 Longstanding persistent atrial fibrillation
 - 148.19 Other persistent atrial fibrillation
 - I48.20 Chronic atrial fibrillation, unspecified*
 - I48.21 Permanent atrial fibrillation
 - I48.91 Unspecified atrial fibrillation
- **3** Secondary diagnosis ICD-10 diagnosis code of Z00.6 Encounter for examination for normal comparison and control in clinical research program
- 4 Condition code 30 Specifying participation in a Qualifying Clinical Trial
- 5 Value code D4 Clinical Trial Number (NCT 02699957) listed on clinicaltrials.gov

*The unspecified code is **NOT COVERED** under NCD 20.34 for LAAC. LAAC claims reported with this diagnosis code will be denied by Medicare.

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

See page 2 for important information about the uses and limitations of this document.



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Professional billing best practices for concomitant procedures

When a WATCHMAN procedure is performed during the same operative episode as a cardiac ablation procedure to treat atrial fibrillation. Medicare applies a Multiple Procedure Payment Reduction to the professional services.

- Multiple Procedure Payment Reduction payment adjustment rule for multiple procedures applies to the service. The WATCHMAN FLX Pro LAAC Device 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 procedure 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 FLX Pro LAAC Device 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 depending upon physician documented medical necessity of the service and timing..

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

Physician Claims Billing

Concomitant Cardiac Ablation and LAAC; same physician

- 1 **CPT® codes 93656 and 33340** Use the pulmonary vein isolation ablation code 33340 (use for either PFA or a thermal ablation modality) as the principal procedure and append modifier -51 to each specifying multiple services
- 2 Primary ICD-10-CM diagnosis code of one of the following:
 - I48.0 Paroxysmal atrial fibrillation
 - I48.11 Longstanding persistent atrial fibrillation
 - I48.19 Other persistent atrial fibrillation
 - I48.20 Chronic atrial fibrillation, unspecified*
 - I48.21 Permanent atrial fibrillation
 - I48.91 Unspecified atrial fibrillation

*The unspecified code is **NOT COVERED** under NCD 20.34 for LAAC. LAAC claims reported with this diagnosis code will be denied by Medicare.



Professional billing best practices for concomitant procedures, continued

- **3 Place of Service code of 21 on both services** Designates both services as inpatient due to CMS restriction of LAAC procedure to the Inpatient Only services list (IPO)
- 4 **Secondary diagnosis code Z00.6** Encounter for examination for normal comparison and control in clinical research program
- 5 **Modifier Q0** Investigational service provided in a clinical research study to indicate patient participation in the LAAO registry
- 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).



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Reimbursement considerations for concomitant Cardiac Ablation and LAAC: commercial payer implications

Site of Service

Unlike Medicare and Medicare Advantage plans where LAAC and therefore concomitant LAAC + AF ablation are on the "Inpatient Only" services list, commercial payers may choose to authorize and reimburse for LAAC procedures and/or concomitant AF ablation + LAAC procedures when performed in the inpatient **or outpatient** setting of care.

	Medicare	FFS/MA*	Comm	nercial
	Inpatient (IP)	Outpatient (OP)	Inpatient (IP)	Outpatient (OP)
Concomitant AF ablation + LAAC	Covered	Not Covered	Potentially Covered (PA/PD required)	Potentially Covered (PA/PD required)

*MA plans may not cover concomitant cases in an OP site of service due to LAAC IPO status in Medicare, however MA plans frequently do require prior authorization (PA) or pre-determination (PD).

Establishing Contractually Agreed upon Reimbursement Rates for Concomitant Procedures

Hospitals will need to pursue contracting with commercial payers for concomitant AF ablation + LAAC procedures in both settings of care, despite there not being a Medicare mechanism nor any publicly available payment rate for concomitant procedures in the outpatient setting of care. It's critical to confirm with the hospital that commercial payer contracts are updated to reflect mutually agreed-upon reimbursement frameworks and amounts for both standalone LAAC procedures as well as for concomitant procedures in either an inpatient or an outpatient site of service.

Physician Services Payment

Like CMS, commercial payers may require use of modifiers and/or apply a multiple procedure payment reduction when a physician performs more than one procedure on the same date of service. Consult your payer reimbursement policies.

Р	Procedure	CPT [®] Code	Physician Work RVUs	Total RVUs*	2025 Medicare National Rate ³
PVL	/AF Ablation	93656	17.00	27.72	\$897
	LAAC	33340	14.00	22.87	\$740

*Total RVUs are comprised of the physician work RVU (wRVU), practice expense RVU (PE RVU), and professional liability insurance RVU (PLI RVU).

3. CMS CY2025 Physician Fee Schedule (PFS) Final Rule: CMS 1807-F, including related PFS addenda. Conversion Factor used in calculations = \$32.3465. Effective through December 31, 2025.

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Reimbursement considerations for concomitant cardiac ablation and LAAC, continued

Productivity Contracting

From an employment contract perspective, it's important to understand whether wRVUs are being used to quantify physician productivity or to quantify reimbursable services. It's important that providers take time to review compensation agreements to assess if and how RVU reductions are applied along with the established reasoning and negotiate changes, as appropriate. The overall goal should be that the employer is providing an organizationally consistent opportunity for reasonable credit of work that is performed.

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 FLX LAAC Device 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.



Centers for Medicare & Medicaid Services

https://www.cms.gov/medicare-coverage-database/view/ncacal-decision-memo.aspx?proposed=N&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 \geq 2 (Congestive heart failure, Hypertension, Age >75, Diabetes, Stroke/transient ischemia attack/thrombo-embolism) or CHA₂DS₂-VASc score \geq 3 (Congestive heart failure, Hypertension, Age \geq 65, Diabetes, Stroke/transient ischemia attack/thromboembolism, Vascular disease, Sex category)
- A formal shared decision-making interaction with an independent noninterventional 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

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NATIONAL COVERAGE DETERMINATION (NCD 20.34)

Continued

- 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
- 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 \ge 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

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





Patient decision aid

https://www.nice.org.uk/guidance/ng196





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

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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 FLX FLX Pro LAAC Device procedures 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 plans are administered by Medicare Advantage Organizations (MAO). Effective as of January 1, 2024, CMS mandates that Medicare Advantage plans align their coverage and site of service with Medicare FFS guidelines. CMS implements important utilization management policy and coverage criteria protections to ensure Medicare Advantage enrollees receive the same access to medically necessary care that they would receive in Traditional Fee-for-service Medicare.

https://www.cms.gov/newsroom/fact-sheets/2024-medicare-advantage-and-part-d-final-rule-cms-4201-f

Medicaid

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

Please contact:

WATCHMAN.Reimbursement@bsci.com





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 FLX Pro LAAC Device in advance of performing the procedure.

Please refer to the WATCHMAN Download Center for the most up-to-date list of WATCHMAN FLX Pro LAAC Device 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/health-economics-and-reimbursement.html

COMMERCIAL HEALTH INSURANCE

WATCHMAN FLX Pro LAA												
Health Plan	Primary Service Area	Health Plan	Primary Service Area									
AETNA	National	BCBS of FL (Florida Blues)	FL									
AmeriHealth	PA, NJ, DC	BCBS of IL	IL									
Arkansas Health	AR	BCBS of Kansas	KS									
Anthem	National	BCBS of Kansas City	KS									
Anthem Blue Cross of California	CA	BCBS of Louisiana	LA									
Anthem Blue Cross of Colorado	СО	BCBS of MA	MA, RI									
Anthem Blue Cross of Connecticut	СТ	BCBS of MI	MI									
Anthem Blue Cross of Indiana	IN	BCBS of MN	MN									
Anthem Blue Cross of Kentucky	KY	BCBS of MS	MS									
Anthem Blue Cross of Maine	ME	BCBS of MT	MT									
Anthem Blue Cross of Missouri	MI	BCBS of NC	NC									
Anthem Blue Cross of Nevada	NV	BCBS of ND	ND									
Anthem Blue Cross of New Hampshire	NH	BCBS of NM	NM									
Anthem Blue Cross of Nevada	NV	BCBS of Northeast NY	NY									
Anthem Blue Cross of Ohio	ОН	BCBS Western NY	NY									
Anthem Blue Cross of Virginia	VA	BCBS of OK	ОК									
Anthem Blue Cross of Wisconsin	WI	BCBS of RI	RI									
AvMed	FL	BCBS of SC	SC									
Blue Cross Blue Shield of Georgia	GA	BCBS of TN	TN									
Empire Blue Cross Blue Shield	NY	BCBS of TX	ТХ									
Unicare	FL	BCBS of Wyoming	WY									
BCBS of AL	AL	BCBS of Federal Employee Program	National									
BCBS of AR	AR	Blue Cross ID	ID									
BCBS Health Advantage	ТХ	Blue Shield CA	CA									
BCBS of AZ	AZ	Capital Health Plan	FL									

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COMMERCIAL HEALTH INSURANCE

Continued

Health Plan	Primary Service Area	Health Plan	Primary Service Area
Capital Bluecross	PA	Health New England	MA, CT
CareFirst BCBS	DC, MD, VA	Highmark BCBS	DE, PA, WV
CareSource	ОН	Horizon BCBS	NJ
Centene	National	Humana	National
Arizona Complete	AZ	Independence Blue Cross	PA
Arkansas Total	AR	LifeWise	OR, WA
Buckeye Health	ОН	Medica	MN
Coordinated Care	WA	Medical Mutual of Ohio	ОН
Heath Net CA	CA	Nebraska Blue	NE
Health Net OR	OR	Optima (Sentara)	VA, OH, NC, WV, FI, MD, PA SC, GA, CA
Magnolia Health	MS	Preferred One	MN
Peach State Health	GA	Premera Blue Cross	WA, AK, OR
PA Health and Wellness	PA	Prevera 360	WI
Cigna	National	Priority Health	MI
Coordinated Care Health Plan	WA	Regence Health Plan (Regence Blue Cross Blue Sheild)	IA, OH, UT, WA
Dean Health Plan	WI	Scott & White Health Plan	ТХ
Emblem Health	NY, CT, NJ, FI, PA, NC, MA, SC, GA, CA	Summa Health	OH, MD
Excellus	NY, CT	TriCare	National
Fallon	MA, NY, CT, FL, PA, SC	Tufts Health Plan	MA, RI, NY
Group Health	WA	UPMC	PA
Harvard Pilgrim	MA, ME, CT, NH, RI, VT, NY	United Healthcare	National
Hawaii Medical Services Association (HMSA)	н	Univera	NY
Health Alliance of MI	MI	Wellmark Blue Cross Blue Shield	IA, SD

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.

See page 2 for important information about the uses and limitations of this document.



Additional resources for health economics and 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 FLX Pro LAAC Device programs. Please use the following website to register:

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



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

The webinar topics below are available on-demand.

Coding and Claims for WATCHMAN FLX Pro LAAC Device procedure

- Understanding WATCHMAN FLX Pro LAAC Device assigned DRGs
- Importance of Documentation
- Review of claims processing for institution and physician

National Coverage Determination

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

Resources Supporting Prior Authorization, Appeals and Beyond

- Best practices and tools
- Review of Boston Scientific resources
- Commercial payor landscape for WATCHMAN FLX Pro LAAC Device coverage

Any questions regarding these webinars can be directed to WATCHMAN.Reimbursement@bsci.com