# WATCHMAN FLX LAAC DEVICE REIMBURSEMENT GUIDE

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

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

Email: WATCHMAN.Reimbursement@bsci.com

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

The FDA Approved the WATCHMAN FLX LAAC Device on July 21, 2020.

To access the WATCHMAN FLX LAAC Device approval document, visit the FDA website

**WATCHMAN FLX™ – eIFU 51221704**

**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 "Instructions for Use" for more information on Indications, Contraindications, Warnings, Precautions, Adverse Events, and Operator's Instructions.

**INTENDED USE/INDICATIONS FOR USE**

The WATCHMAN FLX 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 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 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 Closure Device (see **Table 45** of the eIFU).
- The patient has a known hypersensitivity to any portion of the device material or the individual components (see Device Description section of the eIFU) such that the use of the WATCHMAN FLX 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 Device should only be performed by interventional cardiologists and/or electrophysiologists who are trained in percutaneous and transseptal procedures and who have completed the WATCHMAN FLX Physician Training program.

- 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 echocardiographic imaging guidance in multiple views (TEE recommended in multiple angles [e.g., 0°, 45°, 90°, 135°]) to avoid improper Closure Device sizing.
- Do not release (i.e., unscrew) the WATCHMAN FLX Device from the core wire unless all release criteria 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.
- Appropriate post-procedure drug therapy should be followed. See Post-Procedure Information section (of the eIFU) for further detail.

**PRECAUTIONS**

- The safety and effectiveness (and benefit-risk profile) of the WATCHMAN FLX 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 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.

**PATIENT SELECTION FOR TREATMENT**

**In considering the use of the WATCHMAN FLX Device, the rationale for seeking an alternative to long-term anticoagulation therapy and the safety and effectiveness of the device compared to anticoagulation should be taken into account.**

- The presence of indication(s) for long-term anticoagulation therapy, other than non-valvular atrial fibrillation (e.g. mechanical heart valve, hypercoagulable states, recurrent deep venous thrombosis).

Details regarding the indications, contraindications, warnings, and precautions for oral anticoagulants approved for patients with non-valvular atrial fibrillation are provided in their respective Instructions for Use.

Of note:

- The safety and effectiveness (and benefit-risk profile) of the WATCHMAN FLX Device has not been established in patients for whom long-term anticoagulation is determined to be contraindicated.

Factors that need to be considered for the WATCHMAN FLX Device and implantation procedure include the following:

- Overall medical status, including conditions which might preclude the safety of a percutaneous, transcatheter procedure.
- Suitability for percutaneous, transseptal procedures, including considerations of:
  - Cardiac anatomy relating to the LAA size and shape.
  - Vascular access anatomy (e.g., femoral vein size, thrombus, or tortuosity).
  - Ability of the patient to tolerate general or local anesthesia.
  - Ability of the patient to undergo required imaging.
- Ability to comply with the recommended post-WATCHMAN FLX Device implant pharmacologic regimen (see Post-Procedure Information section) especially for patients at high risk for bleeding.

**ADVERSE EVENTS**

Potential adverse events (in alphabetical order) which may be associated with the use of a left atrial appendage closure device or implantation procedure include but are not limited to: Air embolism, Airway trauma, Allergic reaction to the contrast media, anesthetic, WATCHMAN Implant material, or medications, 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, Myocardial erosion, Nausea, Oral bleeding, Pericardial effusion/tamponade, Pleural effusion, Prolonged bleeding from a laceration, Pseudoaneurysm, Pulmonary edema, 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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## WATCHMAN FLX Left Atrial Appendage Closure Device 2022 Reimbursement Guide

# 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.



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<br>23.13 Total RVUs |
| Diagnosis Codes | **ICD-10-CM Diagnosis Codes**<br>**I48.91** Unspecified Atrial Fibrillation<br>**I48.20** Chronic Atrial Fibrillation, Unspecified*<br>**I48.21** Permanent Atrial Fibrillation<br>**I48.0** Paroxysmal Atrial Fibrillation<br>**I48.11** Longstanding Persistent Atrial Fibrillation<br>**I48.19** Other Persistent Atrial Fibrillation | |
| Coverage | **Original Medicare** – CMS National Coverage Determination (NCD CED 20.34) establishes uniform coverage criteria[1]<br>**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 Patients[2]<br>**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/medicare-advantage-plans-cover-all-medicare-services

# ICD-10-CM DIAGNOSIS CODES

## 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 were 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 End Date September 30, 2019 | Current Code Assignment FY 2020 – Effective October 1, 2019 |
|---|---|
| **I48.91** Unspecified Atrial Fibrillation | **I48.91** Unspecified Atrial Fibrillation |
| **I48.2** Chronic Atrial Fibrillation | **I48.20** Chronic Atrial Fibrillation, Unspecified* |
| **I48.0** Paroxysmal Atrial Fibrillation | **I48.21** Permanent Atrial Fibrillation |
| **I48.1** Persistent 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 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. | |
| **MS-DRG** | **MS-DRG Description** | **FY 2022 National Average Payment*** |
| MS-DRG 273 | Percutaneous Intracardiac Procedures with MCC | $25,234 |
| MS-DRG 274 | Percutaneous Intracardiac Procedures without MCC | $21,673 |

*Centers for Medicare and Medicaid Services. Medicare Program: FY2022 Hospital Inpatient Prospective Payment System, Final Rule; September, 2021.

https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Internet-Only-Manuals-IOMs-Items/CMS018912.html

# HOSPITAL REIMBURSEMENT

Continued

## Transesophageal Echocardiogram (TEE) — Baseline and Follow-Up

| Code | Description | APC | CY 2022 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 | $493 |

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

## Computed Tomography (CT) — Baseline and Follow-Up

| Code | Description | APC | CY 2022 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). | 5571 | $182 |
| 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). | | |

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

# HOSPITAL REIMBURSEMENT

Continued

## Transesophageal Echocardiogram (TEE) — Intraoperative

| Code | Description | APC | CY 2022 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.

# PHYSICIAN REIMBURSEMENT

## WATCHMAN FLX LAAC Device Procedure

| Code | Description | RVU | CY 2022 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<br>23.13 Total RVUs | $800 |

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

**Same Physician Performing Implant and Intraoperative TEE**

CPT 33340 (WATCHMAN FLX LAAC Device) 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.

# PHYSICIAN REIMBURSEMENT
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 2022 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<br>7.14 Total NonFacility RVUs<br>3.14 Total Facility RVUs (-26) | Global $247<br>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.

# PHYSICIAN REIMBURSEMENT

Continued

## Computed Tomography (CT) — Baseline and Follow-Up

| Code | Description | RVU | CY 2022 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<br>5.17 NonFacility Total RVUs<br>2.45 Facility Total RVUs (-26) | Global $244<br>Professional $85 |
| 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<br>7.51 NonFacility Total RVUs<br>3.34 Facility Total RVUs (-26) | Global $348<br>Professional $116 |

**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.

# PHYSICIAN REIMBURSEMENT

Continued

## Transesophageal Echocardiogram (TEE) — Intraoperative

| Code | Description | RVU | CY 2022 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<br>6.62 Total RVUs | $229 |

*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 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.

# 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
- 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

# CMS 1500 Claim Example for WATCHMAN™ FLX LAAC Device

## HEALTH INSURANCE CLAIM FORM

APPROVED BY NATIONAL UNIFORM CLAIM COMMITTEE (NUCC) 02/12

PICA

1. MEDICARE (Medicare#) MEDICAID (Medicaid#) TRICARE (ID#/DoD#) CHAMPVA (Member ID#) GROUP HEALTH PLAN (ID#) FECA BLK LUNG (ID#) OTHER (ID#)

1a. INSURED'S I.D. NUMBER (For Program in Item 1)

2. PATIENT'S NAME (Last Name, First Name, Middle Initial)

3. PATIENT'S BIRTH DATE MM DD YY SEX M F

4. INSURED'S NAME (Last Name, First Name, Middle Initial)

5. PATIENT'S ADDRESS (No., Street)

6. PATIENT RELATIONSHIP TO INSURED Self Spouse Child Other

7. INSURED'S ADDRESS (No., Street)

CITY STATE

8. RESERVED FOR NUCC USE

CITY STATE

ZIP CODE TELEPHONE (Include Area Code) ( )

ZIP CODE TELEPHONE (Include Area Code) ( )

9. OTHER INSURED'S NAME (Last Name, First Name, Middle Initial)

10. IS PATIENT'S CONDITION RELATED TO:

11. INSURED'S POLICY GROUP OR FECA NUMBER

a. OTHER INSURED'S POLICY OR GROUP NUMBER

a. EMPLOYMENT? (Current or Previous) YES NO

a. INSURED'S DATE OF BIRTH MM DD YY SEX M F

b. RESERVED FOR NUCC USE

b. AUTO ACCIDENT? PLACE (State) YES NO

b. OTHER CLAIM ID (Designated by NUCC)

c. OTHER ACCIDENT? YES NO

c. INSURANCE PLAN NAME OR PROGRAM NAME

d. 0d. CLAIM CODES (Designated by NUCC)

d. IS THERE ANOTHER HEALTH BENEFIT PLAN? YES NO *If yes*, complete items 9, 9a, and 9d.

12. SIGNING THIS FORM. ease of any medical or other information necessary

13. INSURED'S OR AUTHORIZED PERSON'S SIGNATURE I authorize payment of medical benefits to the undersigned physician or supplier for services

SIGNE

14. 16. DATES FROM OCCUPATION DD YY

17. 18. HOSPIT FROM SERVICES DD YY

19. ADDITIONAL CLAIM INFORMATION (Designated by NUCC)

20. OUTSIDE LAB? YES NO $ CHARGES

21. DIAGNOSIS OR NATURE OF ILLNESS OR INJURY Relate A-L to service line below (24E) ICD Ind. 0

A. I480 B. Z006 C. D.

E. F. G. H.

I. J. K. L.

22. RESUBMISSION CODE ORIGINAL REF. NO.

23. PRIOR AUTHORIZATION NUMBER CT02699957

| 24. A. DATE(S) OF SERVICE From MM | DD | YY | To MM | DD | YY | B. PLACE OF SERVICE | C. EMG | D. PROCEDURES, SERVICES, OR SUPPLIES (Explain Unusual Circumstances) CPT/HCPCS | MODIFIER | E. DIAGNOSIS POINTER | F. $ CHARGES | G. DAYS OR UNITS | H. EPSDT Family Plan | I. ID. QUAL. | J. RENDERING PROVIDER ID. # |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| 1 | 01 | 01 | 17 | 01 | 02 | 17 | 21 | | 33340 | Q0 | A,B | | 1 | | NPI | |
| 2 | | | | | | | | | | | | | | | NPI | |
| 3 | | | | | | | | | | | | | | | | |
| 4 | | | | | | | | | | | | | | | | |
| 5 | | | | | | | | | | | | | | | | |
| 6 | | | | | | | | | | | | | | | NPI | |

CARRIER

PATIENT AND INSURED INFORMATION

PHYSICIAN OR SUPPLIER INFORMATION

Item 21A designates the primary diagnosis codes as required by Medicare. One of the following diagnosis codes are allowed:
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 the CMS NCD for LAAC. Some private payers have included this ICD-10 code in their coverage policy

Item 21B designates the secondary ICD-10-CM diagnosis code Z00.6 (Encounter for examination of participant in clinical research program) to indicate the patient is participating in the LAAO registry.

Item 23 designates the National Clinical Trial (NCT) number for the Left Atrial Appendage Occlusion (LAAO) registry.

Item 24B designates place of service (POS) 21 for inpatient hospital as required by Medicare.

Item 24D designates the CPT Code 33340 for the WATCHMAN™ FLX LAAC Device.

Item 24D designates the HCPCS modifier Q0 (Investigational service provided in a clinical research study) to indicate the patient is participating in the LAAO registry.

Sources:
Items 21A-21B & 24B-24D) CMSMedicare Claims Processing Transmittal 3515; Medlearn Matters Number MM9638 Item 23-1) CMS Medicare Medlearn Matters Number MM9638; Claims Processing Transmittal 2955
Item 23-2) Left Atrial Appendage Occlusion Registry, clinicaltrials.gov; https//www.cms.gov/Medicare/Coverage/Coverage-with-Evidence-Development/LAAC.html
Item 24D) Official AMA CPT code description 33340 Percutaneous transcatheter closure of the left atrial appendage with endocardial implant, including fluoroscopy, transseptal puncture, catheter placement(s), left atrial angiography, left atrial appendage angiography, when performed, and radiological supervision and interpretation.

IC-420005-AD

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

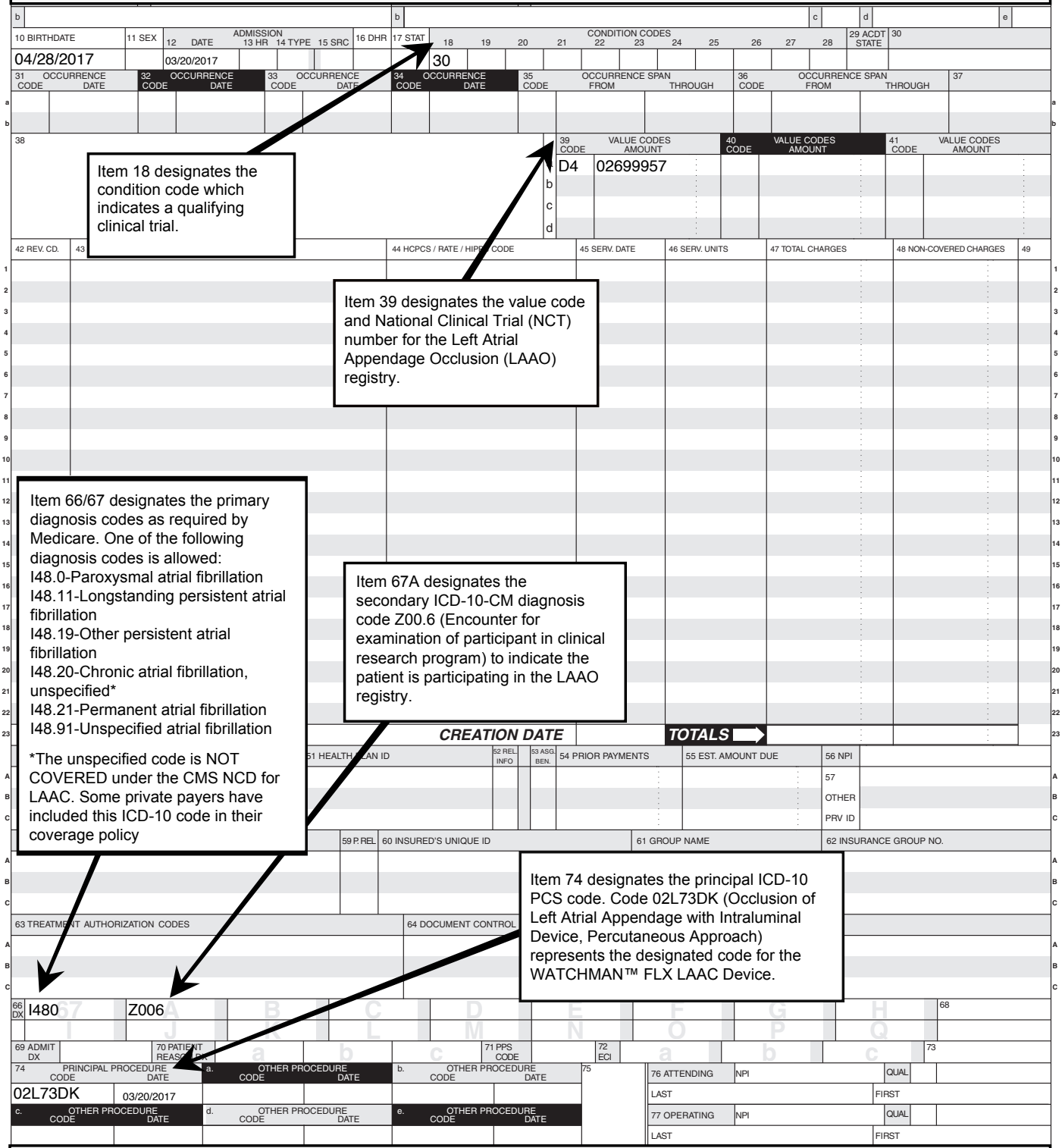
*The unspecified code is **NOT COVERED** under the CMS NCD for LAAC. Some private payers have included this ICD-10-CM code in their coverage policy

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/icd-10/2022-icd-10-cm

# CMS Inpatient UB-04 Claim Example for WATCHMAN™ FLX LAAC Device




Sources:

- Left Atrial Appendage Occlusion Registry, clinicaltrials.gov, https//www.cmsgov/Medicare/Coverage/Coverage/Coverage-with-Evidence-Development/LAAC.html
- CMS Manual System, Pub 100-04 Claim Processing, Transmittal 3515; https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/Downloads/R3515CP.pdf

IC-471408-AB

# INSTITUTIONAL HOSPITAL CLAIMS BILLING INSTRUCTIONS

Continued

## Device C-Code

The WATCHMAN FLX LAAC Device is classified by Medicare as an "Inpatient Only" procedure therefore no HCPCS device category C-code exists for WATCHMAN FLX 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 July 1, 2020.

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 FLX LAAC 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 Approach

- **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 FLX LAAC 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 FLX 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/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 FLX LAAC 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 FLX 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 FLX LAAC 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 FLX 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 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 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.

CMS.gov
Centers for Medicare & Medicaid Services

https://www.cms.gov/medicare-coverage-database/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 $CHADS_2$ score ≥ 2 (Congestive heart failure, Hypertension, Age >75, Diabetes, Stroke/transient ischemia attack/thrombo-embolism) or $CHA_2DS_2$-VASc score ≥ 3 (Congestive heart failure, Hypertension, Age ≥ 65, Diabetes, Stroke/transient ischemia attack/thromboembolism, Vascular disease, Sex category)
- A formal shared decision-making interaction with an independent non-interventional physician using an evidence-based decision tool on oral anticoagulation in patients with NVAF prior to LAAC. Additionally, the shared decision-making interaction must be documented in the medical record.

# 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.

ACP American College of Physicians
Leading Internal Medicine, Improving Lives

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

NICE National Institute for Health and Care Excellence
Patient decision aid

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

CardioSmart American College of Cardiology

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
- The procedure must be performed by an interventional cardiologist(s), electrophysiologist(s) or cardiovascular surgeon(s) that meet the following criteria:

## NATIONAL COVERAGE DETERMINATION (NCD 20.34)

Continued

  - 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 FLX 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 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 FLX 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 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 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

Continued

## WATCHMAN FLX LAAC Device Private Payer Coverage (August 2021)

| 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 | CO | BCBS of MA | MA, RI |
| Anthem Blue Cross of Connecticut | CT | 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 | OH | BCBS Western NY | NY |
| Anthem Blue Cross of Virginia | VA | BCBS of OK | OK |
| Anthem Blue Cross of Wisconsin | WI | BCBS of RI | RI |
| Blue Cross Blue Shield of Georgia | GA | BCBS of SC | SC |
| Empire Blue Cross Blue Shield | NY | BCBS of TN | TN |
| Unicare | FL | BCBS of TX | TX |
| AvMed | 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 | TX | Blue Shield CA | CA |
| BCBS of AZ | AZ | Capital Health Plan | FL |

# COMMERCIAL HEALTH INSURANCE

Continued

## WATCHMAN FLX LAAC Device Private Payer Coverage (August 2021) 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 | OH | Horizon BCBS | NJ |
| Centene | National | Humana | National |
| Arizona Complete | AZ | Independence Blue Cross | PA |
| Arkansas Total | AR | LifeWise | OR, WA |
| Buckeye Health | OH | Medica | MN |
| Coordinated Care | WA | Medical Mutual of Ohio | OH |
| 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 | TX |
| 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) | HI | 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.

# 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 FLX LAAC Device programs. Please use the following website to register:

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 below are available on-demand.**

**Coding and Claims for WATCHMAN FLX LAAC Device procedure**

- Understanding WATCHMAN FLX 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 LAAC Device coverage

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