

Medical Necessity & Coverage Assessment

NAME: _____ ☐ MALE ☐ FEMALE DOB _____/_____/_____ MD _____ INSURANCE _____

THE FOLLOWING CLINICAL DOCUMENTATION IS SUPPORTED WITHIN PATIENT CHART NOTES, WHICH ARE INCLUDED

1. Diagnosis & Stroke Risk

Non-valvular atrial fibrillation with diagnostic evidence included
Elevated stroke risk (CHA₂DS₂-VASc Score _____)
Stroke risk rationale provided

Documented?

- ☐ YES
☐ YES
☐ YES

2. Anticoagulation History

Anticoagulants tried with dates
Duration of therapy documented
Adherence, tolerance, or safety concerns documented
HAS-BLED score _____

Documented?

- ☐ YES
☐ YES
☐ YES
☐ YES

3. Guideline-Aligned Considerations

(Generalized categories reflecting themes aligned with 2023 ACC/HRS/SCAI/AF Management guidelines, commonly referenced in payer policies and public comments to the CMS NCD)

Select all that apply, and document details:

- ☐ Contraindication to long-term OAC (class IIa, B-NR)
☐ History of major bleeding
☐ High bleeding risk (HAS-BLED, frailty, fall risk, occupational risk (class IIb, B-R)
☐ Intolerance or adverse effects from OAC
☐ Drug interaction concerns
☐ Patient-specific factors (renal dysfunction, lifestyle, adherence challenges)
☐ Clear clinical conclusion that long-term OAC is not safe or appropriate

4. Shared Decision-Making Encounter

Conducted by an independent, non-interventional physician
Evidence-based decision tool used

Documented?

- ☐ YES
☐ YES

5. Imaging and Clinical Evidence

Imaging evidence of anatomical suitability
Each clinical risk factor must have a corresponding note, lab value, or medication listed

Documented?

- ☐ YES
☐ YES

6. Medical Necessity Statement

Explicit statement that WATCHMAN is medically necessary based on:

- ☐ NVAf diagnosis
☐ Elevated stroke risk
☐ Contraindication or unsuitability for long-term OAC (2023 ACC/HRS/SCAI AF Management guideline recommendations)
☐ Shared decision-making encounter
☐ Multidisciplinary team review
☐ Procedural candidacy

CHA₂DS₂-VASc Calculator

	Risk factor	If pt has risk factor, add points
C	Congestive Heart Failure	+1
H	Hypertension (including normal BP on blood pressure medications)	+1
A ₂	Age 75 years or older	+2
D	Diabetes	+1
S ₂	Stroke or TIA	+2
V	Vascular Disease	+1
A	Age 65-74 years	+1
Sc	Sex Category: Female sex	+1
Total:		

HAS-BLED Scoring Tool

	Risk Factor	Points
H	Hypertension SBP >160mmHg	+1
A	Abnormal Renal Function	+1
S	Stroke History	+1
B	Bleeding Hx or Predisposition	+1
L	Labile INR	+1
E	Elderly >65 years	+1
D	Drugs (Antiplatelets or NSAIDs)	+1
D	Alcohol drinks >8/week	+1
Total:		

CMS ELIGIBILITY (MAY DIFFER FOR COMMERCIAL PAYER; PLEASE REFERENCE AND INCLUDE POLICY)

- Increased risk for stroke and systemic embolism based on CHADS₂ score ≥2 or CHA₂DS₂VASc score ≥3.
- A formal shared decision-making interaction with an independent non-interventional physician using an evidence-based decision tool on oral anticoagulation in patients with NVAf prior to LAAC. Additionally, the shared decision-making interaction must be documented in the medical record.
- A suitability for short-term warfarin but deemed unable to take long-term oral anticoagulation following the conclusion of shared decision making, as LAAC is only covered as a second line therapy to oral anticoagulants.
- The patient, both pre-operatively and post-operatively, will be 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.
- Procedure performed by trained EP, IC or Cardiac surgeon that meet the following criteria:
 - Has received training prescribed by the manufacturer on the safe and effective use of the device prior to performing LAAC; and,
 - Has performed ≥25 interventional cardiac procedures that involve transeptal puncture through an intact septum; and,
 - Continues to perform ≥25 interventional cardiac procedures that involve transeptal puncture through an intact septum, of which at least 12 are LAAC, over a 2-year period.
- The patient is enrolled in, and the MDT and hospital must participate in a prospective, national, audited registry. Registries must be reviewed and approved by CMS.

*Centers for Medicare & Medicaid Services (CMS). National Coverage Determination (NCD) for Percutaneous Left Atrial Appendage Closure (LAAC) (20.34). Effective February 8, 2016.

I certify that I am an Electrophysiologist, Interventional Cardiologist, or Cardiovascular Surgeon who has received required manufacturer training.

- **I have performed more than 25 interventional cardiac procedures with transseptal puncture through an intact septum.**
- **Within the last 2 years, I have performed more than 25 interventional cardiac procedures involving transseptal puncture through an intact septum.**
- **Within the last 2 years, at least 12 of the more than 25 interventional cardiac procedures I have performed have been LAAC procedures.**

MD SIGNATURE _____

DATE ____/____/____

CMS encourages the use of an evidence-based tool in physician and patient discussions to help document the appropriateness of LAAC as a non-pharmacological treatment option in comparing the risk-benefit to anticoagulants. I certify that I have received the documented shared decision-making result from an independent, non-interventional physician and have confirmed that the patient remains an appropriate candidate to receive a WATCHMAN™ device.

MD SIGNATURE _____

DATE ____/____/____

Based on the included assessment, the patient meets 2023 AF Guideline class (IIa/IIb) _____ criteria and has the clinical rationale, supported by the CMS.National.Coverage.Determination.or Commercial.Policy, to receive a WATCHMAN device as the patient has an elevated stroke risk (CHA₂DS₂-VASc _____), a documented contraindication to long-term oral anticoagulation, imaging confirming anatomical suitability for LAAO, and a bleeding risk (HAS-BLED _____) that makes continued anticoagulation unsafe, thereby establishing that LAAO is medically necessary as an evidence-based alternative.

MD SIGNATURE _____

DATE ____/____/____