

PATIENT SELECTION

Nonvalvular Atrial Fibrillation

As defined by the ACC/AHA Task Force in 2014:¹ *Nonvalvular AF is AF in the absence of rheumatic mitral stenosis, a mechanical or bioprosthetic heart valve, or mitral valve repair.*

Appropriate Rationale to Seek a Non-pharmacologic Alternative to Warfarin

From page 2 of the *WATCHMAN™ Device Directions for Use*, specific factors may include one or more of the following:²

- A history of major bleeding while taking therapeutic anticoagulation therapy.
- The patient’s prior experience with oral anticoagulation (if applicable), which may include an inability to maintain a stable therapeutic International Normalized Ratio (INR) or inability to comply with regular INR monitoring AND unavailability of an approved alternative anticoagulation agent.
- A medical condition, occupation, or lifestyle placing the patient at high risk of major bleeding secondary to trauma.

REFERENCES

1. January CT, et al. 2014 AHA/ACC/HRS guideline for the management of patients with atrial fibrillation: executive summary: a report of the ACC/AHA Task Force on Practice Guidelines and the Heart Rhythm Society. *J Am Coll Cardiol.* 2014;64:2246–80.
2. WATCHMAN Device DFU (90746221-01C).

PATIENT SELECTION

CMS Coverage

- CHADS₂ score ≥ 2 or a CHA₂DS₂-VASc score ≥ 3
- Patients must be **suitable for short-term warfarin, but deemed unable to take long-term oral anticoagulation** (see note below)
- Documented evidence of a formal shared decision interaction between the patient and an independent, non-interventional physician

Suitability for Short-Term Warfarin, but Unable to Take Long-Term Anticoagulation

From page 70 of the CMS Decision Memo (CAG-00445N):¹ The ACC/HRS/SCAI consensus public comment listed contraindications to long-term warfarin therapy.

These include the following:

- History of intracranial bleeding (intracerebral or subdural) where benefits of LAAC outweigh risks
- History of spontaneous bleeding other than intracranial (e.g., retroperitoneal bleeding)
- Documented poor compliance with anticoagulant therapy after patient education
- Inability or significant difficulty with maintaining patients in therapeutic anticoagulation range with use of guidelines
- Intolerance of warfarin and new oral anticoagulants (NOACs)
- High risk of recurrent falls
- Cognitive impairment
- Severe renal failure
- Occupation related high bleeding risk
- Need for prolonged dual antiplatelet therapy
- Increased bleeding risk not reflected by the HAS-BLED score (e.g., thrombocytopenia, cancer, or risk of tumor associated bleeding in case of systemic anticoagulation)
- Other situations for which anticoagulation is inappropriate.

REFERENCES

1. <https://www.cms.gov/medicare/coverage/coverage-with-evidence-development/laac.html>