

The Watchman device is FDA approved for patients with non-valvular AF who have a CHA₂DS₂VASC score ≥ 2 and also have a history of bleeding or major risk for significant bleeding with anticoagulation. WATCHMAN has non-inferiority to Coumadin. Here at PAMF, we are being a bit more stringent and requiring that they also fail Eliquis, because it has superiority to Coumadin and a lower bleeding risk, and are not a curative ablation candidate.

For more detailed criteria on whether your patient meets inclusion criteria see below:

1. Non-valvular atrial fibrillation, with **no other reasons for anticoagulation therapy** such as mechanical prosthetic valve, hypercoagulable states, recurrent DVT/PE.
2. **No contraindications to short term aspirin and Coumadin** (required for 45 days and Aspirin/Plavix for the next 5 months)
3. Have an increased risk for recurrent stroke or systemic embolism based on **CHA₂DS₂VASC score ≥ 2**
4. Subject is a candidate for OAC and Watchman is being considered as an alternative therapy because:
 - a. **History of major bleeding**, (e.g., intracranial hemorrhage or GI bleed requiring hospitalization) while taking therapeutic anticoagulation therapy
 - b. **Inability to maintain a stable therapeutic International Normalized Ratio (INR)** or inability to comply with regular INR monitoring AND intolerance of an approved alternative anticoagulation agent
 - c. A medical condition placing the patient at ***high risk of major life threatening bleed.**

*Unique situations associated with frequent falls, occupation, or lifestyle choices that pose unacceptable risk of head injury are potential candidates only after careful discussion.

At PAMF,

Not ablation candidate

Not NOAC candidate