



June 28, 2023

Ms. Tamara Syrek Jensen  
Director, Coverage and Analysis Group  
Centers for Medicare & Medicaid Services  
Center for Clinical Standards and Quality  
7500 Security Boulevard Baltimore, MD 21244

Mr. Larry Young  
Director, Medicare Contractor Management Group  
Centers for Medicare & Medicaid Services  
Center for Medicare  
7500 Security Boulevard Baltimore, MD 21244

*Sent electronically via email.*

RE: National Coverage Determination 20.34 Percutaneous Left Atrial Appendage Closure (LAAC)  
Clarification

Dear Ms. Syrek Jensen and Mr. Young:

We are writing on behalf of the Heart Rhythm Society (HRS), the Society for Cardiovascular Angiography and Interventions (SCAI), and the American College of Cardiology (ACC) to address a concern regarding Medicare Administrative Contractor (MAC) interpretation of the shared decision-making requirement of the Percutaneous Left Atrial Appendage Closure (LAAC) National Coverage Determination.

The discrepancy stems from MAC interpretation of the following requirement:

*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.*

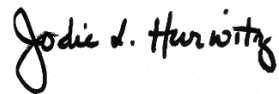
It has long been HRS', SCAI's, and the ACC's understanding that this requirement refers to a separate physician (interventional cardiologist or electrophysiologist) that is not implanting the device. However, several MACs have begun sending CERT denials, indicating that the shared decision making cannot be done by an interventional cardiologist or electrophysiologist even if they are not the implanting physician.

As interventional cardiologists and electrophysiologists often provide general cardiovascular care for patients with atrial fibrillation, a non-implanting interventional cardiologist or electrophysiologist should be allowed to perform the shared decision-making as intended. In fact, based on their experience with catheter-based procedures, interventional cardiologists and electrophysiologists probably provide more insightful advice for the shared decision-making process.

Respectfully, we request to meet with CMS to clarify the intent of the shared decision-making requirement. Further, we request that CMS provide education to the MACs to ensure the NCD language for shared decision-making is properly understood. Please let us know when a meeting can be scheduled for this purpose.

Thank you for your consideration of this request. Should you have any questions, please contact Lisa Miller at [LMiller@hrsonline.org](mailto:LMiller@hrsonline.org), Monica Wright at [MLWright@scai.org](mailto:MLWright@scai.org), or Amanda Stirling at [astirling@acc.org](mailto:astirling@acc.org).

Sincerely,



**Jodie L. Hurwitz, MD, FHRS**  
President, Heart Rhythm Society



**B. Hadley Wilson, MD, FACC**  
President, American College of Cardiology



**George D. Dangas, MD, PHD, MSCAI**  
President, Society for Cardiovascular Angiography & Interventions