



AMERICAN
COLLEGE of
CARDIOLOGY



December 10, 2015

Ms. Tamara Syrek-Jensen
Director, Coverage & Analysis Group
Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244

RE: Proposed National Coverage Decision (NCD) Memorandum for Percutaneous Left Atrial Appendage Closure (LAAC) Therapy (CAG-00445N)

Dear Ms. Syrek-Jensen:

The American College of Cardiology (ACC), Heart Rhythm Society (HRS), and Society for Cardiovascular Angiography and Interventions (SCAI) are the non-profit professional associations representing the majority of practicing interventional cardiologists and electrophysiologists in the United States. These members have expertise and experience in the treatments and therapies for stroke prevention. ACC, HRS and SCAI appreciate the opportunity to submit joint comments on the proposed National Coverage Decision for percutaneous left atrial appendage closure (LAAC). This document represents the consensus of the three societies.

Summary

CMS's proposal to cover LAAC for non-valvular atrial fibrillation (AF) patients with elevated risk of stroke performed by experienced operators at high quality facilities with data reported to a registry after a shared decision-making discussion is a significant and positive step for these patients. The societies support this framework for coverage. However, the societies also recommend revisions to certain details and requirements within that framework that will further ensure that the correct patients are receiving this therapy and that unnecessary administrative obstacles are not created.

- Specifically, the societies provide recommendation on appropriate contraindications to anticoagulation that would support coverage as described in Appendix A.
- With respect to institutional and operator requirements we recommend CMS rely on the peer-reviewed document published online today in the *Journal of the American College of Cardiology*, *HeartRhythm*, and *Catheterization and Cardiovascular Interventions*. The societies recommend CMS utilize the standards included in that document in place of the previously proposed requirements. These important changes are reflected in the attached redline version of the NCD.
- The societies question the scientific basis of the proposed requirement for data collection on contemporaneous patients managed with oral anticoagulant (OAC) therapy to serve as non-interventional controls and recommend it be removed.
- Currently, an evidence-based tool is not available for the anticipated patient population who may be treated with LAAC. As an alternative, the societies suggest an algorithm (Appendix B) as

a decision-making tool to assist in determining the most appropriate treatment pathways for patients.

Comments pertaining to each of the proposed seven conditions for coverage are presented below. In addition, a redline version of suggested changes to the language proposed by CMS in the draft coverage policy is attached.

1. FDA-approved Device

Available evidence aligns with the proposed condition that the device used to close the LAA should be approved by the Food and Drug Administration (FDA) for non-valvular AF. In comparison to non-valvular AF, insufficient evidence exists to support coverage of patients with valvular AF. The higher risk of left atrial thrombus outside the appendage in patients with rheumatic valvular disease suggests that patient population is not currently suitable for this therapy.

2. Patient Characteristics

FDA approval for the Watchman, the only device currently with specific indications for this use, is for patients who have a high CHADS2 or CHA2DS2-VASc score. CMS also proposes to use a high CHADS2 or CHA2DS2-VASc score as a condition of coverage. The societies agree that a high score on this metric should be required for coverage, but suggest that it be further defined. Specifically, the policy should state a threshold of *a CHADS2 score greater than or equal to 2 or a CHA2DS2-VASc score greater than or equal to 3.*

The rationale for a patient to seek a non-pharmacologic alternative to warfarin will likely include the conditions captured in a HAS-BLED score. As such, the societies again suggest a numerical score be included. Specifically the policy should explicitly state that high bleeding risk be defined as a HAS-BLED score of greater than or equal to 3. While these thresholds for high stroke risk and high bleeding risk are to some degree arbitrary, sufficient expert opinion exists to support their use.

CMS also proposes to provide coverage to patients who have a contraindication to long-term warfarin therapy. The societies recommend CMS use the list of contraindications included in Appendix A as a guide to specific patient populations who could potentially fall into this category.

The draft policy, as written, requires patients to have a high CHADS2 or CHA2DS2-VASc score, high HAS-BLED score, AND contraindication to warfarin. Mandating that all three of these requirements be met would prevent patients who may not reach the HAS-BLED threshold but have long-term contraindications to anticoagulation from qualifying for coverage. Such patients would benefit from LAAC. More consistent with the FDA indications, the societies strongly recommend qualifying patients who have a high CHADS2 or CHA2DS2-VASc score AND EITHER a high HAS-BLED score OR a contraindication to warfarin. The redline attachment presents this solution.

3. & 4. Institutional and Operator Requirements

As with other recent emerging technologies, the societies have worked together to develop recommendations for the appropriate qualifications for both, operators and institutions to optimize effectiveness and patient safety. That peer-reviewed document was published online today in the *Journal of the American College of Cardiology*, **HeartRhythm**, and *Catheterization and Cardiovascular*

Interventions. It is also attached with these comments. The societies strongly recommend CMS utilize the standards for both operators and institutions included in that document in place of the previously proposed requirements. These important changes regarding the appropriate criteria required to qualify operators and institutions are reflected in the attached redline version of the NCD.

5. Device-specific Training

CMS proposes that operators must undergo training “by the device manufacturer on the safe and effective use of the device prior to performing implant procedures” by a physician who already has experience implanting the device. In the draft policy CMS proposes that a new operator be supervised for a minimum of two cases and observed for a minimum of 2 cases. The proposal also includes a requirement that the training physician not be a representative of the manufacturer.

While the societies agree that proctors should be free of undue influence, proctors need to be compensated for their time and travel. The Societies recommend that the NCD conform to prior training requirements for procedures such as Transcatheter Aortic Valve Replacement (TAVR). Specifically, the Societies recommend that:

- Physician proctors be selected on the basis of their experience, knowledge of the procedure and teaching skills;
- The Societies wholly endorse the concept that proctors be free of undue influence by manufacturers.; and,
- Quality proctors need to be compensated and we believe it would be counterproductive to have proctors who have no remuneration for their time and expertise and no relationship with the device manufacturer.

Revisions are proposed in the attached redline that are more consistent with previous NCDs such as those formulated for TAVR

6. Participation in a National Registry

As with other recent coverage with evidence development (CED) NCDs for cardiovascular therapies such as Transcatheter Aortic Valve Replacement, CMS proposes that physician teams must participate in a prospective national registry that consecutively enrolls all LAAC patients and tracks certain outcomes for at least five years.

The societies expect all operators and institutions to participate in an LAAC registry. The LAA Occlusion Dataset as part of the National Cardiovascular Data Registry (NCDR) LAA Occlusion Registry has already been developed. Previous meetings between FDA, CMS, the societies, as well as NCDR suggest that some mechanism of adjudication will be provided by the registry sponsors for strokes through the first two years after implantation. The existing design of the LAA Occlusion Dataset will allow tracking of all seven parameters specified in the Proposed Decision Memo, with the caveat that adjudication of strokes as currently proposed by the sponsor and the FDA is limited to two years after implantation, although site reporting will continue beyond that window. CMS’s proposal to review the qualifications of the registry is consistent with other recent CED policies.

In addition to collection of data on complications and outcomes of LAAC, CMS proposes participating registries must also “include contemporaneous patients followed on oral anticoagulant (OAC) therapy to serve as non-interventional controls.” For this population, the term “control” is inaccurate. The “non-

interventional controls” would in fact represent a widely mismatched group that should not be comparable to patients who receive the device. The societies strongly object to this requirement and recommend its deletion.

- Such a requirement violates the standards of scientific integrity and relevance to the Medicare population referenced in the proposed NCD. While the desire to obtain information on a control group undergoing oral anticoagulation is understandable, that has been the subject of two well conducted trials that randomized patients, using a model and scientific rigor that could not remotely be replicated with the proposed control arm.
- Moreover, such a control arm would require that every institution performing LAAC set up an elaborate screening process, obtain investigational review board approval, and seek informed consent from patients and follow up from patients, most of whom may be seen entirely in an outpatient setting by a myriad of clinicians few of whom will have any involvement with LAAC.
- The “non-interventional controls” would in fact be largely mismatched with the patients who receive the device. The proposed control arm would constitute a research study with skewed selection and will be of limited if any benefit from a research or public health standpoint.

In sum, observational comparisons of patients who are treated with procedures versus those who are treated without interventions are highly prone to bias and other confounding factors which would severely limit any useful clinical information which could be obtained from such an undertaking in addition to all the other associated problems as described above.

7. Formal Shared Decision-making

Coverage of LAAC would also be contingent upon documentation of a formal shared decision-making interaction between the patient and physician using an “evidence-based decision tool” on anticoagulation. The societies support the role of shared decision-making but caution that the level of evidence base required for an “evidence-based decision tool” as used in other settings is not available for this patient population which is being proposed in the draft NCD proposal. As an alternative, the societies propose the use of a decision algorithm as outlined in appendix B as a guide to appropriate treatment pathways that is consistent with current clinical practice.

Coverage of Clinical Trials

In benchmarking this draft NCD with similar CED LCDs for transcatheter cardiovascular therapies, it was noted that a section explicitly covering LAAC in clinical trials is not included in the LAAC draft NCD. It is not clear from the draft whether CMS intends to cover LAAC in clinical trials since no definitive statement is included other than that, “All CMS-approved clinical studies and registries must adhere to” a list of standards relevant for scientific integrity and relevance to the Medicare population. NCD 310.1 governing coverage of costs in clinical trials should apply, but the absence of clinical trial coverage is concerning. To remove uncertainty and confusion regarding CMS’s intent, the societies recommend the NCD be revised to expressly state that, “LAAC is covered within a clinical trial consistent with NCD 310.1 which provides coverage for the routine costs of qualifying clinical trials.” This revision is also presented in the redline attachment.

The societies look forward to working with you through the rest of the coverage process. If you have questions or need additional information regarding any of these comments, please contact James

Vavricek at jvavricek@acc.org, Kim Moore at kmoore@hrsonline.org, or Dawn Gray at dhopkins@scai.org.

Sincerely,

A handwritten signature in black ink that reads "Jim Blankenship". The letters are cursive and fluid.

James C. Blankenship, MD, MSc, FSCAI
SCAI President

A handwritten signature in black ink that reads "John D. Day". The signature is highly stylized and cursive.

John D. Day, MD, FHRS
HRS President

A handwritten signature in black ink that reads "Kim A. Williams, Sr.". The signature is cursive and includes a small flourish at the end.

Kim Allan Williams, Sr., MD, FACC, FAHA, FASNC
ACC President

Enclosures

Appendix A

Contraindications to Anticoagulation

1. History of intracranial bleeding (intracerebral or subdural) where benefits of LAAC outweigh risks
2. History of spontaneous bleeding other than intracranial (e.g. retroperitoneal bleeding)
3. Documented poor compliance with anticoagulant therapy
4. Inability or significant difficulty with maintaining patients in therapeutic anticoagulation range
5. Intolerance of warfarin and NOACs
6. High risk of recurrent falls
7. Cognitive impairment
8. Severe renal failure
9. Occupation related high bleeding risk
10. Need for prolonged dual antiplatelet therapy
11. 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)
12. Other situations for which anticoagulation is inappropriate

Appendix B

Recommended Algorithm for Decision Making

Non-valvular atrial fibrillation with high risk for OAC for stroke/embolism prevention (CHADS₂ ≥ 2 or CHA₂DS₂-VASc ≥ 3)



