LAAC NCD Redline Edits

A. The Centers for Medicare & Medicaid Services (CMS) proposes that the evidence is sufficient to determine percutaneous left atrial appendage closure (LAAC) therapy using an implanted device is not reasonable and necessary to diagnose or treat an illness or injury or to improve the functioning of a malformed body member and, therefore, is not covered under § 1862(a)(1)(A) of the Social Security Act.

B. In order to support evidence development for technologies likely to show benefit for the Medicare population, CMS proposes to cover items or services that are reasonable and necessary for research under §1862(a)(1)(E) of the Social Security Act using the Coverage with Evidence Development (CED) paradigm. We propose that coverage would be limited to items and services in clinical studies that meet the conditions specified below:

Percutaneous LAAC therapy is covered for patients with non-valvular atrial fibrillation only, when all of the following conditions 1-7 are met.

1. - The device is FDA approved for patients with non-valvular atrial fibrillation.

2. - The patient has:
   - A high CHADS2 ≥ 2 (Congestive heart failure, Hypertension, Age >75, Diabetes, Stroke/transient ischemia attack/thromboembolism) or CHA2DS2-VASc score ≥ 3, (Congestive heart failure, Hypertension, Age ≥ 65, Diabetes, Stroke/transient ischemia attack/thromboembolism, Vascular disease, Sex category); and, either
   - A high HAS-BLED score ≥ 3 (Hypertension, Abnormal renal function and/or liver function, Stroke, prior Bleeding, Labile anticoagulation range, Elderly age>65, Drug therapy such as antiplatelet drugs), ~~and~~ or
   - A contraindication to long-term warfarin therapy as defined in Appendix A.
3. The procedure is furnished in a hospital ~~that meets the following institutional requirements:~~ with an established structural heart disease (SHD) and/or electrophysiology (EP) program, as well as the physical space and ancillary services to execute the procedure effectively and safely that meets the following key institutional requirements:

   ~~a. - Cardiac catheterization lab or electrophysiology (EP) lab with fluoroscopy capability~~

   ~~b. - Non-invasive imaging (i.e. transesophageal echocardiography) with dedicated echocardiography support~~

   ~~c. - Anesthesiology support for administration of general anesthesia specific to this procedure~~

   ~~d. - Cath lab, operating room (if required), post anesthesia recovery, intensive care and step down unit space to accommodate cases with and without complications~~

   ~~e. - On-site emergency cardiac surgery services~~

   1. - Institutional volume
      An aggregate of 50 structural heart disease or left-sided catheter ablations, at least 25 of which involve transseptal puncture through an intact septum, should be performed at the institution in the year leading to starting an LAA occlusion program and per year thereafter (see Table I from Attachment A-SCAI/ACC/HRS Institutional and Operator Requirements for Left Atrial Appendage Occlusion for a list of qualifying left-sided procedures). The rationale is that not only the primary procedural specialist or physician team, but also ancillary staff, should be comfortable with the basic aspects of the procedure.

2. - Procedural area
    a. - The procedure should be performed in the cardiac catheterization laboratory, electrophysiology suite, or hybrid suite with continuous hemodynamic monitoring.
    b. - Fixed radiographic imaging systems with fluoroscopy, offering catheterization laboratory-quality imaging are required. The capability to acquire/record cine loops is strongly recommended.
    c. - Mobile C-Arm for fluoroscopic imaging is not acceptable.
    d. - Biplane imaging is helpful but not required.
    e. - The room should be adequately sized to accommodate echocardiographic and - anesthesia equipment, in addition to the regular radiographic imaging system. -
    f. - The interventional suite should be stocked with equipment for safe procedures and for handling complications such as device stabilization, retrieval, and managing pericardial effusions. This equipment includes a variety of endovascular sheaths, diagnostic catheters, transseptal kits, wires, snares, bioptomes, vascular occluders, and pericardiocentesis equipment.
    g. - Cell-Saver technology for rapid processing of drained blood and re-transfusion in case of pericardial effusion and tamponade should be readily available.
3. - Echocardiography
    a. - An echocardiography laboratory with the full array of transthoracic and TEE capabilities should be on site.
    b. - A TEE-capable machine and probe should be available in the procedure room.
    c. - Appropriate staff should be present during the procedure, which may include a cardiologist or cardiac anesthesiologist familiar with the procedural steps and subtleties of invasive echocardiography.
    d. - Three-dimensional echocardiography capability is helpful but not required.
4. - Ancillary services
    a. - Multidisciplinary team/Outpatient clinic
    Optimally, an LAA occlusion program should be embedded in a comprehensive AF and structural heart program to allow for comprehensive patient care. The composition of the MDT caring for the patient will vary from site to site. In addition to an electrophysiologist and/or interventional cardiologist (pediatric or adult) or cardiovascular surgeon fully trained in SHD procedures, who will be the primary operator(s) for the procedure, physicians with expertise in procedure-guided TEE, ICE, or management of AF should be available. The composition of the implanting team will vary from center to center. In some institutions, physician teams, consisting of a primary operator along with an assistant or co-operator, may jointly perform the procedure to offer the greatest expertise and to optimize procedural success and safety. In other highly experienced centers, a single procedural specialist may be adequate for device implantation. Physician specialists and technologists skilled in CT and other imaging modality interpretation should be available if procedures that require CT imaging are performed. In addition, a non-physician provider (nurse, nurse practitioner, physician assistant) could be helpful in facilitating the MDT approach.
    b. - Cardiac surgery
    A cardiac surgeon, anesthesiologist, and perfusionist should be on site for surgical backup. Cardiac surgery operating rooms should be readily available in the rare event of a major complication requiring surgical intervention.
    c. - Post-procedural care

After undergoing LAA occlusion, patients can be managed in a post-anesthesia care unit, intensive care unit, or telemetry unit. Personnel experienced in managing patients undergoing complex cardiac procedures must be present.

d. - Blood bank
A blood bank does not have to be on site; however, it is prudent that patients be typed and screened, with packed red-blood cells available if needed.

4. The procedure is performed by physicians with the following qualifications and experience:
   - ~~The primary implanting physician has performed ≥ 25 interventional cardiac procedures involving a trans-septal puncture (TSP) in their total experience, with at least 10 TSP procedures performed over the past 12 month period.~~
   - ~~The primary implanting physician(s) must be an interventional cardiologist and/or an electrophysiologist. They may jointly participate in intra-procedural aspects of the implant or perform the implant procedure individually.~~

   Initial Qualification
   a. - 50 lifetime structural or left-sided catheter ablation procedures, at least 25 of which involved transseptal puncture through an intact septum *.
   b. - Clinical knowledge that includes a comprehensive understanding of stroke and bleeding risk in atrial fibrillation and appropriate treatment strategies.
   c. - Experience with catheter-based management of potential complications, including pericardiocentesis and embolized device retrieval.
   d. - Suitable training on the devices to be used.
   e. Understanding of left atrial appendage anatomy and imaging -
   Ongoing -
   a. - Over a 2-year period, 25 procedures that involve transseptal puncture through an intact septum, 12 of which are LAA occlusion procedures.

Process for identifying whether additional training is required on the basis of technological or clinical changes.

*LAA occlusion involving a transseptal catheterization that is primary (i.e., WATCHMAN or similar devices) or adjunctive to a percutaneous pericardial approach (i.e., LARIAT), percutaneous left ventricular assist device placement when such devices involve transseptal approach (i.e. Tandem Heart), endovascular catheter ablation within the left side of the heart, pulmonary vein stenting, balloon mitral valvuloplasty, percutaneous closure of prosthetic mitral paravalvular leaks using a transseptal approach, antegrade balloon aortic valvuloplasty, mitral valve repair using the MitraClip system or other technique involving transseptal puncture, ASD or PFO closure, and diagnostic transseptal catheterization.

5. - The interventional cardiologist(s) and electrophysiologist(s) must have received the training prescribed by the manufacturer on the safe and effective use of the device prior to performing implant procedures. ~~Training should also include a physician who already has experience implanting the device, but who is not a representative of the manufacturer, as well as a minimum of two supervised and two observed cases.~~

6. - The patient is enrolled in, and the treating physician team is participating in a prospective national registry that consecutively enrolls LAAC patients and tracks the following annual

outcomes at the patient data level for a period of at least five years from the time of the LAAC procedure.

- Operator-specific complications
- Device-specific complications including device thromboses
- Stroke, adjudicated, by type
- TIA
- Systemic embolism
- Death
- Major bleeding, by site and severity

The registry must be designed to permit identification and analysis of patient, practitioner and facility level factors that predict patient risk for these outcomes. ~~The registry must include contemporaneous patients followed on oral anticoagulant (OAC) therapy to serve as non-interventional controls.~~ CMS will review the qualifications of candidate registries to ensure that the approved registry follows standard data collection practices and collects data necessary to evaluate the patient outcomes specified above.

The registry must collect all data necessary to conduct multivariable adjusted analyses and have a written executable analysis plan in place to address the following questions:

In a prospective, clinical study, when percutaneous LAAC therapy using an implanted device is performed outside a randomized, controlled clinical trial, compared to non-interventional controls followed on oral anticoagulant (OAC) therapy:

- How do the outcomes listed above compare to outcomes in the pivotal clinical trials in the short term (<12 months) and in the long term (≥ 5 years)?
- ~~How do the outcomes listed above differ from outcomes in comparable concurrent OAC controls in the short term (<12 months) and in the long term (>5 years)?~~
- What is the long term (≥ 5 year) durability of the device?
- What are the short term (<12 months) and the long term (>5 years) device-specific - complications including device thromboses? -

7. - A formal shared decision-making interaction between the patient and provider ~~using an evidence-based decision tool on anticoagulation in patients with NVAF must occur prior to LAAC,~~ must be documented in the medical records, must include a discussion of the benefits and harms, must document an appropriate rationale to seek a non-pharmacologic alternative to anticoagulants, taking into account the safety and effectiveness of the device compared to anticoagulants, and have, after being informed of the reported risks of LAAC and reasonable alternative management strategies, given informed consent. A treatment algorithm is provided to assist in this process in Appendix B.

C. LAAC is covered within a clinical trial consistent with NCD 310.1 which provides coverage for the routine costs of qualifying clinical trials.

D. All CMS-approved clinical studies and registries must adhere to the following standards of scientific integrity and relevance to the Medicare population:

a. The principal purpose of the study is to test whether the item or service meaningfully improves health outcomes of affected beneficiaries who are represented by the enrolled subject
b. The rationale for the study is well supported by available scientific and medical evidence.
c. The study results are not anticipated to unjustifiably duplicate existing knowledge.
d. The study design is methodologically appropriate and the anticipated number of enrolled subjects is sufficient to answer the research question(s) being asked in the National Coverage Determination.
e. The study is sponsored by an organization or individual capable of completing it successfully.
f. The research study is in compliance with all applicable Federal regulations concerning the protection of human subjects found in the Code of Federal Regulations (CFR) at 45 CFR Part 46. If a study is regulated by the Food and Drug Administration (FDA), it is also in compliance with 21 CFR Parts 50 and 56. In addition, to further enhance the protection of human subjects in studies conducted under CED, the study must provide and obtain meaningful informed consent from patients regarding the risks associated with the study items and/or services, and the use and eventual disposition of the collected data.
g. All aspects of the study are conducted according to appropriate standards of scientific integrity.
h. The study has a written protocol that clearly demonstrates adherence to the standards listed here as Medicare requirements.
i. The study is not designed to exclusively test toxicity or disease pathophysiology in healthy individuals. Such studies may meet this requirement only if the disease or condition being studied is life threatening as defined in 21 CFR §312.81(a) and the patient has no other viable treatment options.
j. The clinical research studies and registries are registered on the www.ClinicalTrials.gov website by the principal sponsor/investigator prior to the enrollment of the first study subject. Registries are also registered in the Agency for Healthcare Quality (AHRQ) Registry of Patient Registries (RoPR).
k. The research study protocol specifies the method and timing of public release of all prespecified outcomes to be measured including release of outcomes if outcomes are negative or study is terminated early. The results must be made public within 12 months of the study's primary completion date, which is the date the final subject had final data collection for the primary endpoint, even if the trial does not achieve its primary aim. The results must include number started/completed, summary results for primary and secondary outcome measures, statistical analyses, and adverse events. Final results must be reported in a publicly accessibly manner; either in a peer-reviewed scientific journal (in print or on-line), in an on-line publicly accessible registry dedicated to the dissemination of clinical trial information such as ClinicalTrials.gov, or in journals willing to publish in abbreviated format (e.g., for studies with negative or incomplete results).
l. The study protocol must explicitly discuss beneficiary subpopulations affected by the item or service under investigation, particularly traditionally underrepresented groups in clinical studies, how the inclusion and exclusion criteria effect enrollment of these populations, and

a plan for the retention and reporting of said populations in the trial. If the inclusion and exclusion criteria are expected to have a negative effect on the recruitment or retention of underrepresented populations, the protocol must discuss why these criteria are necessary.

m. -The study protocol explicitly discusses how the results are or are not expected to be generalizable to affected beneficiary subpopulations. Separate discussions in the protocol may be necessary for populations eligible for Medicare due to age, disability or Medicaid eligibility.

Consistent with section 1142 of the Act, the Agency for Healthcare Research and Quality (AHRQ) supports clinical research studies that CMS determines meet the above-listed standards and address the above-listed research questions. All other indications are nationally non-covered.

The principal investigator must submit the complete study protocol, identify the relevant CMS research question(s) that will be addressed and cite the location of the detailed analysis plan for those questions in the protocol, plus provide a statement addressing how the study satisfies each of the standards of scientific integrity (a. through m. listed above), as well as the investigator's contact information, to the address below. The information will be reviewed, and approved studies will be identified on the CMS website.

Director, Coverage and Analysis Group
Re: LAAC Therapy CED
Centers for Medicare & Medicaid Services (CMS)
7500 Security Blvd., Mail Stop S3-02-01
Baltimore, MD 21244-1850

SCAI/ACC/HRS Institutional and Operator Requirements for Left Atrial Appendage Occlusion

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I. Preamble

Ischemic stroke remains a significant risk for patients with atrial fibrillation (AF). The Food and Drug Administration (FDA) approval of the WATCHMAN device for percutaneous closure of the left atrial appendage (LAA) represents an important addition to the physician's armamentarium to help mitigate this problem. The evolution of LAA occlusion technology has spanned nearly two decades and three FDA panel hearings, leading to FDA approval in 2015. As this technology becomes clinically available to a broader population of patients, it is essential that physician stakeholders establish criteria for the performance of these procedures that will be used in granting initial and ongoing privileges. These criteria are offered to support The Joint Commission mandate that medical staff privileges be granted on the basis of professional criteria specified in the medical staff bylaws to ensure safe and effective patient-centered care. The emergence of transcatheter valve therapies has provided a model whereby multiple societies collaborate to provide recommendations to institutions and operators to assess their potential to establish and maintain programs for these therapies (1-3). As an extension of this concept, the Society of Cardiovascular Angiography and Interventions (SCAI), the Heart Rhythm Society (HRS), and the American College of Cardiology (ACC) agreed to provide recommendations to institutions and interested physicians for the establishment and maintenance of LAA occlusion programs. An initial multi-society overview of the field of LAA occlusion has recently been published, highlighting the critical issues surrounding LAA occlusion therapies (4). This document states that the questions of who should perform these procedures and the institutional support required need further delineation. It is these issues that are the subject of this, the

second multi-society document. As LAA occlusion is in its early developmental stages, the recommendations must initially rely on expert consensus. As experience with LAA occlusion grows, these recommendations will be revised and updated based on expanded expertise and published data. However, the recent FDA approval of the first percutaneous LAA occlusion device underscores the need to make initial recommendations now; this will provide a starting point for future modifications. The recommendations that follow were reviewed by the entire writing committee, with at least 70% concurrence required in order to be incorporated.

In accordance with the partnering societies' policies on relationships with industry and other entities (RWI), relevant author disclosures are included in Appendix 1. In addition, authors' comprehensive RWI information, which includes RWI not relevant to this document, is available online as a data supplement [http://jaccjacc.acc.org/Clinical_Document/SCAI_LAAO_Author_Comprehensive_RWI_Table.pdf] To avoid actual, potential, or perceived conflicts of interest as a result of industry relationships or other personal conflicts, members of the writing committee and the peer reviewers of this document were asked to disclose all present or prior (within 12 months before the initiation of this clinical document) potential conflicts. The writing committee includes a majority of members without relevant RWI and is chaired by an interventional cardiologist, with an additional interventional cardiologist and an electrophysiologist serving as Co-chairs. Authors with relevant RWI were not permitted to draft or vote on content or recommendations pertaining to their RWI. RWI were reviewed during conference calls and updated as changes occurred. Author and peer reviewer RWI pertinent to this document are disclosed in Appendices 1 and 2, respectively. The work of

the writing committee was supported exclusively by the partnering societies without commercial support. Writing committee members donated their time for the preparation of this document. Conference calls of the writing committee were closed and attended only by committee members and society staff. The respective executive boards of the three professional societies provided final review and approval of the document.

SCAI, HRS, and ACC hope that adherence to the recommendations in this document will ensure safe and effective LAA occlusion technology dissemination for stroke prevention in patients with AF in the United States.

II. Introduction

Multiple large, prospective randomized clinical trials have demonstrated that oral anticoagulants such as warfarin, factor Xa inhibitors, and direct thrombin inhibitors are highly effective in reducing the risk of stroke and are the standard of care for many patients with AF at increased risk of thromboembolic events as assessed by $CHADS_2VASC$ score (5-7). These agents, while effective, are associated with an increased risk of bleeding. Some patients with AF whose stroke risk profile would normally warrant anticoagulation have absolute or relative contraindications to anticoagulants. As a result, there is agreement that non-pharmacologic treatment for stroke prevention has been an unmet need, which has stimulated the development of alternatives to pharmacologic therapies. Several approaches to LAA occlusion have evolved simultaneously, including endovascular occlusion, surgical suturing, stapling, and amputation (8). These methods have been shown to vary in their efficacy and safety. The WATCHMAN device has been evaluated in two

randomized clinical trials and two continued access registries encompassing >2400 patients and 6,000 patient-years (9-12). On the basis of the clinical trials data, the FDA approved the WATCHMAN device recently for patients with non-valvular AF who are at risk for stroke, suitable for anticoagulation, and for whom there is a rationale for seeking a non-pharmacologic alternative (http://www.accessdata.fda.gov/cdrh_docs/pdf13/p130013a.pdf). Given the enrollment criteria, many patients who may achieve the greatest clinical benefit from this technology have never been studied in randomized trials of LAA occlusion. SCAI, HRS, and ACC support expanded clinical trials of LAA occlusion that include such patients with the hope that this will lead to refinements in eligibility criteria.

Percutaneous LAA occlusion has the potential to a have major, positive clinical impact on our treatment of certain subsets of patients with AF that are at risk for stroke. LAA occlusion techniques are technically challenging. This expert consensus statement outlines our proposed institutional and operator requirements in order to assist with the implementation of credentialing standards and help providers to participate responsibly, safely, and effectively in this new and important field. The safe application of LAA occlusion requires specific cognitive and technical skillsets and respect for the high-risk nature of these interventions. Procedural specialists[1] performing LAA occlusion will come from a variety of backgrounds, including interventional cardiology (adult or pediatric), electrophysiology, and cardiac surgery. It is expected that physicians will operate within the context of a multidisciplinary team (MDT) to optimize patient selection and clinical

[1]This document will use the term "procedural specialist" to apply to members of any subspecialty who implant LAA occlusion devices.

benefit. The defining principle is that LAA occlusion is an institutionally based therapy provided across multiple disciplines. Patient-centered care is defined by the Institute of Medicine as "health care that establishes a partnership among practitioners, patients, and their families to ensure that decisions respect patients' wants, needs, and preferences and that patients have the education and support to make decisions and participate in their own care" (13). Patient-centered care will be a guiding principle in the implementation of this novel interventional therapy. To this end, physicians participating in LAA occlusion programs must work together in the context of a larger system of health that includes stakeholders from multiple disciplines with overlapping skillsets. The notion of multi-disciplinary teams was first validated in the surgical arena and has gained traction more recently with the evolution of percutaneous valve therapies (1,3,14,15). It is therefore expected that stroke prevention in AF in general, and LAA occlusion in particular, will be a collaborative effort of physician and non-physician experts that may include electrophysiologists, interventional cardiologists, neurologists, imaging experts, primary care providers, cardiac surgeons, and others.

III. Background

Although large randomized clinical trials have demonstrated the efficacy of oral anticoagulant therapy in lowering the risk of stroke and death in patients with AF, the main obstacle to long-term anticoagulant use is major bleeding, which has an incidence of 2%-4%/year (5, 6,7). The traditional anticoagulant, warfarin, is hampered by a narrow therapeutic window, a need for frequent blood testing, and dietary restrictions leading to

patient non-compliance. Novel anticoagulants partially address these issues but are still limited by bleeding and noncompliance (16-19). Although complete elimination of AF would be an attractive alternative strategy in theory, contemporary pharmacologic or invasive radiofrequency ablative therapies have not been shown to reduce stroke risk or to prevent the need for long-term anticoagulant therapy (7, 20). The observation that >90% of thrombi identified in patients with non-valvular AF are found in the LAA has led to the development of mechanical approaches to closing the LAA orifice (21). Several percutaneous approaches to LAA occlusion have been developed through multiple pathways, including the off-label use of FDA-approved devices (LARIAT and atrial or ventricular septal defect closure devices), the use of devices for LAA occlusion available in other countries through their regulatory pathways, and the FDA pivotal trial pathway for class III medical devices (8, 22). Only one such device to date, the WATCHMAN, has received FDA approval for this indication. It is anticipated that this field will grow and the armamentarium of devices for this application will expand. Therefore, it is essential that stakeholders have a thorough understanding of the cognitive and technical aspects surrounding LAA occlusion in general and the various technologies for LAA occlusion currently available and in development.

IV. Cognitive Requirements

Percutaneous LAA occlusion is a new technique, and a significant learning curve for deployment of the WATCHMAN device has demonstrated reduced procedure time, decreased complications, and improved procedural success rates with increasing operator

experience (9,10). The PREVAIL trial was designed in part to evaluate how centers new to the LAA occlusion procedure would perform with respect to procedural complications. Forty percent of the patients were enrolled by new implanters and success and complication rates were not significantly different from those achieved by experienced operators (11). The current pool of trained, experienced operators consists largely of those who have participated in industry-sponsored clinical trials. The introduction of this technology to the wider public and the training of procedural specialists need to be accomplished in a well-designed, controlled, systematic fashion to ensure optimal efficacy and safety. The process in the PREVAIL trial for engaging new centers should serve as a model for establishing new LAA occlusion programs going forward.

Physicians performing this procedure must have a firm grasp of the underlying principles surrounding AF, including:

1) The medical management and clinical course of AF;
2) Principles of rate and rhythm control;
3) Current tools for assessing stroke risk, such as the $CHADS_2$-VASc scoring system;
4) The indications for and management of oral anticoagulant therapy and knowledge of the various agents available;
5) Understanding the risks and benefits of anti-arrhythmic agents used for rate and rhythm control;
6) Understanding the bleeding risks of oral anticoagulants and the use of bleeding risk assessment tools such as the HAS-BLED score;
7) Knowledge of indications, risks, and benefits of invasive surgical and catheter-based ablation techniques; and

8) Knowledge and understanding of shared decision making.

Prior to performing percutaneous LAA occlusion procedures, physicians should have a detailed understanding of the regional anatomy of the heart, including the left atrium and LAA. Knowledge of, and appropriate experience with, transseptal puncture techniques through an intact septum and manipulation of sheaths and catheters within the left atrium, particularly in the context of complex anatomy, are critical (see Table I). Experience with specific procedures requiring access to the left side of the heart is important. These procedures may include:

- LAA occlusion involving a transseptal catheterization that may be primary (i.e., WATCHMAN or similar devices) or adjunctive to a percutaneous pericardial approach (i.e., LARIAT),
- percutaneous left ventricular assist device placement when such devices involve a transseptal approach (i.e. Tandem Heart),
- endovascular catheter ablation within the left side of the heart,
- pulmonary vein stenting,
- balloon mitral valvuloplasty,
- percutaneous closure of prosthetic mitral paravalvular leaks using a transseptal approach,
- antegrade balloon aortic valvuloplasty,
- percutaneous closure of prosthetic mitral paravalvular leaks,
- mitral valve repair using the MitraClip system or other technique involving transseptal puncture,
- ASD or PFO closure, and

- diagnostic transseptal catheterization.

Procedural specialists must be knowledgeable in the interpretation and performance of imaging techniques that pertain directly to understanding the range of anatomic variants of the LAA with respect to size, morphology, and location. Integrating non-invasive imaging data into procedural planning is important for a successful, safe result. Procedural specialists should also be well versed in the indications and contraindications for the procedure. Early recognition of major procedure-related complications such as pericardial effusion/tamponade, air embolism, stroke, and device embolization, and experience in their treatment, including device retrieval, are essential skillsets required for this procedure (23).

V. Procedural Skills and Operator Requirements

There are several devices and approaches for minimally invasive LAA closure (both endocardial and epicardial) at various stages of development (8). In the coming years, these devices and others will probably be available for clinical use in the United States. While there are common principles, each different device technology will also have unique skillsets to be mastered. The number of procedures required for an operator to become fully competent to perform a procedure and those required to maintain competence will vary depending on the complexity of the system being used, operator experience, and an operator's technical and cognitive strengths and weaknesses. Currently, there are no publications establishing data specific to the challenges of LAA occlusion. SCAI has surveyed structural heart program training directors to elicit opinions on the minimum numbers of procedures required to obtain competency for a variety of complex procedures

(24). Most pertinent to LAA occlusion would be transseptal puncture through an intact septum, the average recommended number for which falls in the range of 20-25 per year (25). Similarly, the electrophysiology literature suggests that complications associated with left-sided ablation of AF (requiring transseptal puncture) decrease after 25 procedures (23, 26). Given the limitations of the available data, the writing committee arrived at consensus recommendations for operator requirements for LAA occlusion, which are summarized in Table I.

Operator Skill Sets

As mentioned earlier, each device has unique characteristics that necessitate a consistent, organized training approach provided by the manufacturer that complies with FDA requirements. Before undergoing formal training for a specific device or technique, there are skillsets fundamental to LAA occlusion in which all operators must demonstrate a high level of training, competence, and continued experience. These skill sets are: 1) patient selection, 2) vascular access, 3) access to the left atrium via transseptal puncture, 4) manipulation of large bore sheaths and catheters within the left atrium, and 5) acute and chronic management of complications related to each phase of the procedure.

Patient selection

Proper patient selection is one of the core requirements for the success of any treatment or procedure. There is strong interest among the partnering medical societies in performing LAA occlusion in patients for indications that have not been specifically studied in any of the randomized clinical trials, with the assumption that the theoretical benefits outweigh

the risks. There is strong support for expanding the indications for LAA occlusion beyond those studied in the randomized trials. It is anticipated that the indications for LAA occlusion will expand and refine themselves over time as more clinical data become available. Patients who are at high risk for bleeding or recurrent bleeding, have had significant bleeding on oral anticoagulants, work in high-risk occupations, are unwilling to take or comply with oral anticoagulant therapy, or who are intolerant of anticoagulant therapy, are potential populations that may benefit from this technology and should be studied (27).

Vascular Access and Transseptal Puncture

Fundamental aspects of obtaining vascular access, working with long wires and sheaths, the use of fluoroscopy and contrast agents, and closed loop hemodynamic monitoring systems would be expected to be part of the foundational knowledge base of interventional and invasive electrophysiology training programs, representing level II and III COCATS milestones (24-36 months of training)(23,25, 28). Given the risks associated with transseptal puncture and the importance of being able to accurately localize the puncture site within the interatrial septum, it is expected that operators will be well trained in transseptal puncture before endeavoring to perform LAA occlusion. Alternatively, this skillset may be acquired specifically in the context of performing LAA occlusion under supervision in a high-volume training center with direct participation by an operator experienced in transseptal puncture. The prospective WATCHMAN studies were carried out by procedural specialists who had been performing transseptal puncture “routinely,” where “routinely” had no specific definition (9). It is the writing committee’s consensus

opinion that new operators should have performed 50 lifetime de novo left-sided structural or ablation procedures, 25 of which have involve transseptal puncture through an intact septum *and* should, on an ongoing basis to maintain proficiency, perform at least 25 transseptal punctures over a two-year period, 12 of which are LAA occlusion procedures (> 1 per month) (Table I). In the case of physician teams composed of two operators, at least one of the physicians will be required to meet the qualifying and ongoing proficiency requirements.

It is critical that the procedural specialist employ a standardized, consistent methodology that maximizes transseptal puncture safety, as well as a sophisticated understanding of the relational anatomy that dictates an appropriate location for transseptal puncture. Imaging should include:

1) fluoroscopy— ideally biplane—for visualization of the relational anatomy in the right anterior oblique and left anterior oblique views (these views define the atrio-ventricular groove and septal planes, although it is recognized that a number of alternate fluoroscopic techniques can be effective and safe.);

2) either transesophageal echocardiography (TEE) or intracardiac echocardiography (ICE); and

3) a hemodynamic system to allow for continuous pressure monitoring, which would allow for early recognition of hemodynamic deterioration, including tamponade.

It is important for appendage plug-design closure systems that the implanter has sufficient control and anatomical understanding to place the transseptal puncture at a site that will ideally align the delivery apparatus with the LAA. Typically, this site is posterior and

inferior, although the location will vary depending on the relative height and orientation of the LAA ostium and size of the atria. The implanter needs to understand echocardiographic imaging techniques in order to make this determination with precision. If the procedural specialist relies on TEE guidance for transseptal puncture, familiarity with imaging of the interatrial septum (IAS) in multiple planes to identify the ideal septal target is important. Optimal imaging of the LAA itself typically requires TEE or ICE guidance. However, ICE has not been systematically investigated in terms of its adequacy for LAA imaging for the implant phase of this procedure and is not widely used for this purpose.

Management of Sheaths and Device Delivery in the Left Atrium

Most devices require transseptal wire exchange for a large bore outer diameter sheath. While there are variations in sheath design, there are fundamental practices with which the operator must be adept. Meticulous attention to avoid emboli, either air or thrombus, is a central theme for sheath manipulation since intraprocedural embolic events had significant impact during the learning curve of the PROTECT AF Trial (9). Once the device delivery sheath is in place, operators need to understand the relationship between the sheath and the LAA, atrial roof, pulmonary veins, and posterior atrial wall at all times, as these are all thin-walled structures prone to perforation.

It is usual practice to perform large bore sheath exchanges over a stiff 0.035" guidewire positioned in the left upper pulmonary vein. A pigtail catheter is generally used to position the delivery sheath in the LAA; the depth required for sheath placement will vary depending on device design. With the current WATCHMAN device, it is necessary to advance the sheath fully, through most of the depth of the LAA, and the use of a pigtail

catheter provides an extra measure of safety against perforation. This practice became common as PROTECT AF enrollment progressed, and it may have contributed to the marked decrease in pericardial effusions during the course of the PROTECT AF Trial. Subsequent adoption of this technique may explain in part why new operators had a low (<1%) incidence of tamponade complicating the implants (11).

The LAA is often a multilobar structure, and operators must be able to formulate a 3-D image for proper execution of the procedure. This spatial image of LAA anatomy, largely derived from 2-dimensional imaging data, or increasingly from 3D echo, is used to guide structural heart disease interventions. Assessment of the adequacy of closure must take into account the volume status of the patient at the time of the implant, the true number of lobes requiring closure, an understanding of the ideal sheath curve for a given anatomy, and the motion path of the sheath system in response to clockwise and counterclockwise torqueing.

Management of Complications

The most common potentially serious complication associated with LAA occlusion is pericardial effusion and tamponade. This complication can occur acutely (early) or occasionally insidiously (weeks) following implant (9, 29). It is critical, particularly in the acute presentation, that operators recognize early signs of an effusion so that it can be managed quickly and safely. Continuous hemodynamic monitoring during an implant is essential. There are multiple modalities that can allow a rapid determination of a new effusion, including fluoroscopy (decreased excursion of the left side of the cardiac silhouette often precedes hemodynamic changes) (30), echo imaging, and hemodyamic

monitoring. The implanting physician must be well trained in the basic principles and equipment required to safely access and drain the pericardial space (23).

Once an effusion is identified, the implant team needs to understand the relative risks and benefits and modes of reversing the anticoagulation. It is recommended that the implant team have immediate access to on-site cardiothoracic surgery should uncontrollable bleeding warrant surgical correction. The decision to bring a patient to surgery can be nuanced and requires an experienced implanter who can make this judgment in conjunction with the surgical team. Generally speaking, continued, unabated bleeding should mandate surgical presence and preparation of emergency access to the chest. Centers without an on-site cardiothoracic surgery service available and ready for emergent operation should not have an LAA occlusion implant program. Besides tamponade, the management team must monitor the patient for other complications, including procedure-related stroke, air embolus, and device embolization, all of which are mitigated by sophisticated handling of the sheath delivery system and the anticoagulation status of the patient during the procedure. The procedural specialist should be skilled in retrieval techniques and the use of various forms of bioptomes and snares (23). The implant team should continuously monitor ultrasound images for the presence of thrombus during the case. Having access to an interventional stroke team is advisable to minimize embolic stroke severity should a stroke occur during or after the procedure. There should be a structured program for post-discharge follow up and evaluation by a cardiovascular specialist.

VI. Institutional Requirements

An overview of the institutional requirements to perform percutaneous LAA occlusion has been provided by a recent societal overview co-authored by SCAI, HRS, and ACC (4). The institution should have an established structural heart disease (SHD) and/or electrophysiology (EP) program, as well as the physical space and ancillary services to execute the procedure effectively and safely. Specifically, the writing committee considered the following aspects to be key institutional requirements:

1. Institutional volume

   An aggregate of 50 structural heart disease or left-sided catheter ablations, at least 25 of which involve transseptal puncture through an intact septum, should be performed at the institution in the year leading to starting an LAA occlusion program and per year thereafter (see Table I for qualifying left-sided procedures). The rationale is that not only the primary procedural specialist or physician team, but also ancillary staff, should be comfortable with the basic aspects of the procedure.

2. Procedural area

   a. The procedure should be performed in the cardiac catheterization laboratory, electrophysiology suite, or hybrid suite with continuous hemodynamic monitoring.

   b. Fixed radiographic imaging systems with fluoroscopy, offering catheterization laboratory-quality imaging are required. The capability to acquire/record cine loops is strongly recommended.

   c. Mobile C-Arm for fluoroscopic imaging is not acceptable.

d. Biplane imaging is helpful but not required.

e. The room should be adequately sized to accommodate echocardiographic and anesthesia equipment, in addition to the regular radiographic imaging system.

f. The interventional suite should be stocked with equipment for safe procedures and for handling complications such as device stabilization, retrieval, and managing pericardial effusions. This equipment includes a variety of endovascular sheaths, diagnostic catheters, transseptal kits, wires, snares, bioptomes, vascular occluders, and pericardiocentesis equipment.

g. Cell-Saver technology for rapid processing of drained blood and re-transfusion in case of pericardial effusion and tamponade should be readily available.

3. Echocardiography

a. An echocardiography laboratory with the full array of transthoracic and TEE capabilities should be on site.

b. A TEE-capable machine and probe should be available in the procedure room.

c. Appropriate staff should be present during the procedure, which may include a cardiologist or cardiac anesthesiologist familiar with the procedural steps and subtleties of invasive echocardiography.

d. Three-dimensional echocardiography capability is helpful but not required.

4. Ancillary services

a. Multidisciplinary team/Outpatient clinic

Optimally, an LAA occlusion program should be embedded in a comprehensive AF and structural heart program to allow for comprehensive patient care. The composition of the MDT caring for the patient will vary from site to site. In

addition to an electrophysiologist and/or interventional cardiologist (pediatric or adult) or cardiovascular surgeon fully trained in SHD procedures, who will be the primary operator(s) for the procedure, physicians with expertise in procedure-guided TEE, ICE, or management of AF should be available. The composition of the implanting team will vary from center to center. In some institutions, physician teams, consisting of a primary operator along with an assistant or co-operator, may jointly perform the procedure to offer the greatest expertise and to optimize procedural success and safety. In other highly experienced centers, a single procedural specialist may be adequate for device implantation. Physician specialists and technologists skilled in CT and other imaging modality interpretation should be available if procedures that require CT imaging are performed. In addition, a non-physician provider (nurse, nurse practitioner, physician assistant) could be helpful in facilitating the MDT approach.

b. Cardiac surgery

A cardiac surgeon, anesthesiologist, and perfusionist should be on site for surgical backup. Cardiac surgery operating rooms should be readily available in the rare event of a major complication requiring surgical intervention.

c. Post-procedural care

After undergoing LAA occlusion, patients can be managed in a post-anesthesia care unit, intensive care unit, or telemetry unit. Personnel experienced in managing patients undergoing complex cardiac procedures must be present.

d. Blood bank

A blood bank does not have to be on site; however, it is prudent that patients be typed and screened, with packed red-blood cells available if needed.

VII. Training Models

Effective and efficient acquisition of the technical skills for LAA occlusion can be highly variable and dependent on a variety of factors, including prior experience with complex cardiovascular procedures within the left atrium and associated imaging techniques as well as preferred learning styles. The educational program will provide the background necessary to operators and imaging specialists for successful, consistent, and safe technology delivery. These individuals will be working together as a team. Education may be in the form of a formal didactic course focused on basic principles of the field of LAA occlusion technology. Training should also consist of hands-on experience with procedure equipment, viewing live cases performed by experienced implant teams in an interactive format, and the use of simulation. Finally, proctors who are experienced in LAA occlusion with a specific device should be present to monitor the initial implants performed by the procedural specialist.

During the run-in phase of technology dissemination, operators, clinical specialists, and imaging specialists who took part in the pivotal trials will likely serve as teachers and proctors. As has been observed with other complex cardiovascular procedures, the initial PROTECT AF trials revealed a learning curve with the device (9). In the subsequent PREVAIL study, new operators had similar complication rates to established operators, reflecting improved training methods and the presence of experienced operators acting as proctors (11). Training should entail a review of clinical issues surrounding stroke and

bleeding risk in the setting of AF, the relevant three-dimensional anatomy and imaging of the left atrium and LAA, imaging techniques and planes used to assess closure and appearance of any devices deployed intra- and peri-procedurally, as well as the delivery system and the device (if a device was deployed). Training should also highlight techniques to maximize the likelihood of successful closure/device placement while minimizing the risk of periprocedural complications by acknowledging potential pitfalls and ways to avoid them. The process should build on the disparate yet complementary backgrounds of electrophysiologists, structural interventionalists, and imaging specialists as they relate to transseptal puncture, navigating within the left atrium, and LAA anatomy. Manipulation of the delivery system and device, simulations, and three-dimensional models may form the basis of tactile learning. While theoretical knowledge is requisite when establishing a program, practical experience is desired. Until members of the MDT become proficient, proctoring by physicians or clinical specialists with extensive experience is strongly encouraged. Over time, implantation techniques will likely change as the field evolves and new devices emerge. Therefore, continuing medical education of the MDT will be necessary. Simulation-based education has been shown to be an effective method for learning and for safe implementation of new technology, and the development of simulators for LAA occlusion will undoubtedly become an integral part of a comprehensive training program.

VIII. Quality Assessment

The objective of LAA occlusion is to achieve as complete and proximal a closure of the appendage as possible while maintaining patient safety. Quality measures must be established that evaluate both of these issues over time.

Registry

Registries have been successfully employed for a variety of cardiovascular devices. A recent example is The Society of Thoracic Surgeons/American College of Cardiology Transcatheter Valve Therapy (STS/ACC TVT) registry, which has been developed in collaboration with the FDA, the Center for Medicare and Medicaid Services (CMS), and the Duke Clinical Research Institute (31). This multi-stakeholder registry was proposed in 2011 and is currently in its second iteration; the data have been used by multiple investigators to better understand the clinical use of transcatheter valve therapy. In its approval of the WATCHMAN device, the FDA specified several requirements, including continued follow-up of patients from the initial investigational device exemption (IDE) studies such as PREVAIL, Continuous Access Protocol (CAP), and CAP 2 studies, and a new enrollment study of 1,000 patients implanted with a WATCHMAN device who have agreed to a two-year clinical follow-up (http://www.accessdata.fda.gov/cdrh_docs/pdf13/p130013a.pdf). In addition, the FDA approval stipulated the development, participation, and support of an LAA Occlusion National Cardiovascular Data Registry. The registry will include 1,000 serially implanted patients who are not enrolled in the new enrollment study, and it will be serially linked to the CMS database annually for five years post-implant. The writing committee strongly believes that participation in a national registry should be mandatory for all LAA occlusion programs.

Individual Institutions

Although participation in a registry will likely be mandatory for use of the currently approved device, it is important for individual institutions to have aggregate and operator-specific quality analysis processes. Within institutions, a regular quality analysis process reviewing key metrics, including numbers of implants, complications, and outcomes, should be a standard part of any LAA occlusion program.

After LAA occlusion, results from continued follow-up and the new enrollment study, along with an analysis of national databases, would be beneficial for measuring initial and long-term clinical outcomes. However, individual institutions should have protocols in place for follow-up that include echocardiographic and other imaging data that identify the presence and severity of persistent leaks; medication use (particularly anticoagulants); and clinical outcomes, including bleeding, neurologic events, and device complications.

Table I: LAA Occlusion Program Components

Procedural Specialist*	*Initial Qualification* • 50 lifetime structural or left-sided catheter ablation procedures, at least 25 of which involved transseptal puncture through an intact septum**. • Clinical knowledge that includes a comprehensive understanding of stroke and bleeding risk in atrial fibrillation and appropriate treatment strategies. • Experience with catheter-based management of potential complications, including pericardiocentesis and embolized device retrieval. • Suitable training on the devices to be used. • Understanding of left atrial appendage anatomy and imaging *Ongoing* • Over a 2-year period, 25 procedures that involve transseptal puncture through an intact septum, 12 of which are LAA occlusion procedures. • Process for identifying whether additional training is required on the basis of technological or clinical changes.
Institutional	• 50 structural or left-sided catheter ablations/year, at least 25 of which involved transseptal puncture through an intact septum in the year leading to program initiation and per year thereafter • Continuous intraprocedure availability of a physician with experience at transesophageal echocardiography in structural heart disease (a cardiologist, electrophysiologist, or cardiac anesthesiologist certified in echocardiography and with experience in guiding structural heart interventions may fulfill this role.) • Multidisciplinary team that includes necessary staff and expertise for preoperative evaluation, performing the LAA occlusion procedure, and acute and long-term post-procedure follow-up • Active cardiothoracic surgery program with

	cardiac surgeons and perfusionists on site. • Cardiac catheterization laboratory, electrophysiology laboratory, or hybrid room with hemodynamic monitoring and high resolution imaging.
Data Collection and Quality	• Submission of all cases to a national registry in timely fashion, including follow-up reporting as required. • Institutional multi-stakeholder process for evaluation of patient selection, outcomes, and quality

*Procedures using LAA occlusion devices are typically performed either by electrophysiologists, interventional cardiologists (adult or pediatric), or cardiovascular surgeons. This document uses the term "procedural specialist" to apply to members of any subspecialty who implant LAA occlusion devices. In some cases, a physician team will be composed of two operators; therefore, the procedural volume criteria and ongoing proficiency requirements apply to at least one member of the team.

**LAA occlusion involving a transseptal catheterization that is primary (i.e., WATCHMAN or similar devices) or adjunctive to a percutaneous pericardial approach (i.e., LARIAT), percutaneous left ventricular assist device placement when such devices involve transseptal approach (i.e. Tandem Heart), endovascular catheter ablation within the left side of the heart, pulmonary vein stenting, balloon mitral valvuloplasty, percutaneous closure of prosthetic mitral paravalvular leaks using a transseptal approach, antegrade balloon aortic valvuloplasty, mitral valve repair using the MitraClip system or other technique involving transseptal puncture, ASD or PFO closure, and diagnostic transseptal catheterization.

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Appendix 1-Author Relationships With Industry and Other Entities (Relevant)— SCAI/ACC/HRS Institutional and Operator Requirements for Left Atrial Appendage Occlusion

Committee Member	Employment	Consultant	Speakers Bureau	Ownership/ Partnership/ Principal	Personal Research	Institutional, Organizational, or Other Financial Benefit	Expert Witness
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Kenneth A. Ellenbogen (EP)	Virginia Commonwealth University Medical Center—Director, Clinical Electrophysiology Laboratory	• AtriCure* • Boston Scientific* • SentreHeart • St. Jude Medical*	None	None	• AtriCure* • Boston Scientific* • Medtronic*	• Boston Scientific* • Medtronic*	None
Paul L. Hess (EP)	VA Eastern Colorado Healthcare System, Cardiologist; University of Colorado School of Medicine, Assistant Professor of Medicine	None	None	None	None	None	None
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This table presents the relationships of committee members with industry and other entities that were determined to be relevant to this document. These relationships were reviewed and updated in conjunction with all meetings and/or conference calls of the writing committee during the document development process. The table does not necessarily reflect relationships with industry at the time of publication. A person is deemed to have a significant interest in a business if the interest represents ownership of ≥5% of the voting stock or share of the business entity, or ownership of ≥$5,000 of the fair market value of the business entity; or if funds received by the person from the business entity exceed 5% of the person's gross income for the previous year. Relationships with no financial benefit are also included for the purpose of transparency. Relationships in this table are modest unless otherwise noted.

According to the ACC, a person has a *relevant* relationship IF: a) the *relationship or interest* relates to the same or similar subject matter, intellectual property or asset, topic, or issue addressed in the *document*; or b) the *company/entity* (with whom they have the relationship) makes a drug, drug class, or device addressed in the *document*, or makes a competing drug or device addressed in the *document*; or c) the *person or a member of the person's household*, has a reasonable potential for financial, professional or other personal gain or loss as a result of the issues/content addressed in the *document*.

*Significant relationship.
†No financial benefit

ACC indicates American College of Cardiology; EP, Electrophysiologist; IC, Interventional Cardiologist; and SCAI, Society for Cardiovascular Angiography and Interventions.

Appendix 2-Peer Reviewer Relationships With Industry and Other Entities (Relevant)—SCAI/ACC/HRS Institutional and Operator Requirements for Left Atrial Appendage Occlusion

Reviewer	Representation	Employment	Consultant	Speakers Bureau	Ownership/ Partnership/ Principal	Personal Research	Institutional, Organizational, or Other Financial Benefit	Expert Witness
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Mina K. Chung	HRS	Cleveland Clinic Lerner College of Medicine of Case Western Reserve University	• Boston Scientific* • Medtronic* • St. Jude*	None	None	• Boston Scientific* • Medtronic* • St. Jude*	None	None
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A person has a *relevant* relationship IF: a) the *relationship or interest* relates to the same or similar subject matter, intellectual property or asset, topic, or issue addressed in the *document*; or b) the *company/entity* (with whom the relationship exists) makes a drug, drug class, or device addressed in the *document*, or makes a competing drug or device addressed in the *document*; or c) the *person or a member of the person's household*, has a reasonable potential for financial, professional or other personal gain or loss as a result of the issues/content addressed in the *document*.

* No financial benefit.

ACC indicates American College of Cardiology; HRS, the Heart Rhythm Society; SCAI, the Society for Cardiovascular Angiography and Interventions; and VA, Veterans Affairs.