Is Your Cath Lab Offering **Comprehensive Treatment for Atrial Fibrillation?**

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trial fibrillation (AF) is the most common type $oldsymbol{\Lambda}$ of irregular heartbeat in the United States and is a significant marker of future morbidity, with major consequences for the healthcare delivery system. AF is the cause of about 1 in 7 strokes and tends to cause more severe strokes than other underlying causes, according to statistics from the Centers for Disease Control and Prevention (CDC). AF accounts for more than 454,000 hospitalizations each year, contributes to about 158,000 deaths annually, and has been rising for more than two decades, with estimates that 12.1 million people will have AF by 2030.1 AF has a statistically significant effect on hospital costs and utilization, with the financial impact showing an incremental, annualized increased cost of \$12,789 ± \$161,749 per patient.2 The increase in costs is driven by rates of healthcare encounters, adverse clinical events associated with AF such as stroke, and AF-specific interventions. Overall, the complex nature of AF, and its potential impact on a patient's health and quality of life, can lead to higher healthcare costs.

Stroke prevention is an essential keystone in the treatment of AF, and anticoagulation is the therapy of choice for primary and secondary stroke prevention. But what happens when a patient cannot take anticoagulation? Left atrial appendage occlusion (LAAO) procedures have emerged as an effective alternative to anticoagulation therapy for stroke prevention in AF patients. Several studies have shown that LAAO is a safe and effective treatment option for stroke prevention in AF patients with a contraindication for oral anticoagulants (OAC).3 The decision to offer LAAO procedures in the cardiac catheterization lab (CCL) is complex and involves assessing population needs, clinical expertise, resources, guidelines, and financial considerations. Administrators should carefully consider these factors and engage a multidisciplinary team to ensure the safe and effective implementation of LAAO procedures for eligible patients with AF.

Decision Considerations

Corazon considers several important factors when recommending an organization should start offering more advanced treatment options such as LAAO for AF patients. Three important factors considered are market demand and prevalence of AF in the population, the expertise and resources of the organization, and the financial implications for the organization.

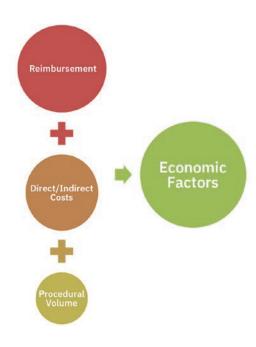


- Market Demand, Patient Population, and Regulatory Factors: Start by conducting a market analysis and assessing the demand for LAAO procedures in your service area, including the prevalence of atrial fibrillation and the number of patients at high risk for stroke. Another factor to consider is referral patterns and patient flows to predict the potential volume of LAAO procedures that your organization may perform and identify opportunities for collaboration with referring physicians, healthcare networks, and patient advocacy groups to increase awareness and access to LAAO procedures. In addition, administrators should be familiar with regulatory requirements and ensure that the new procedure, if initiated, complies with all relevant state and federal guidelines. Be prepared for any auditing or reporting requirements related to the new service.
- Economic Factors: Another important consideration is to evaluate the financial implications of offering LAAO procedures for an organization. Determining the financial feasibility needs to involve a comprehensive evaluation of costs and cost-effectiveness, reimbursement rates, patient volume, and the potential revenue impact on the organization. Key factors to consider in determining the financial viability of offering LAAO procedures include:
 - The reimbursement landscape for LAAO procedures can vary based on factors such as the specific procedure performed, the

patient's insurance coverage, the provider's location, and the payer mix. It is imperative to understand the reimbursement landscape before offering the procedure, including reimbursement rates from government payers (eg, Medicare, Medicaid) and private insurance companies, determine the average reimbursement per procedure, and assess the potential impact on revenue generation for the organization, which is crucial in determining the potential financial viability of offering these procedures.

Medicare sets reimbursement rates for LAAO procedures based on the Current Procedural Terminology (CPT) codes assigned to these services. In some cases, new technologies used in LAAO procedures may be eligible for additional reimbursement through the Medicare New Technology Add-On Payment program. A review of the criteria for this payment option is needed to maximize reimbursement.

Private health insurance companies also have varying reimbursement rates and coverage policies for LAAO procedures such as bundled payment models and prior authorization requirements. Additionally, reimbursement rates for LAAO procedures can differ based on geographic location and local market dynamics. These variances should be considered when assessing the financial impact of offering this advanced service. Administrators should check with individual payers to understand their specific reimbursement guidelines, including proper documentation and coding requirements to receive appropriate reimbursement. Overall, navigating the reimbursement landscape for LAAO procedures requires a comprehensive understanding of payer policies, coding requirements, and documentation standards.



- o As part of the financial analysis, it is recommended that the direct and indirect costs associated with offering LAAO procedures, including physician fees, facility fees, device costs, staff training, and equipment maintenance be calculated. The cost of the LAAO device itself is a significant expense and prices can vary depending on the various manufacturer. It is essential to negotiate pricing agreements with suppliers to ensure cost-effectiveness. Additionally, consideration for costs related to patient care, such as pre-procedural assessments, follow-up visits, and potential complications or readmissions, should also be determined. Offering LAAO procedures may require additional staffing, equipment, and facility resources. Factor in these costs when assessing the financial feasibility of adding LAAO services.
- o Projecting the volume of LAAO procedures can help estimate the potential revenue generated from offering these procedures. Consider factors like patient demand, referral patterns, and competition from other providers when analyzing data and market research for providing projections. Conducting market research to understand the demand for LAAO procedures in the local healthcare market is essential and involves analyzing population demographics, prevalence of AF, and competitor offerings. Analyzing historical data on similar procedures, such as other cardiovascular interventions or AF treatments, can provide insights into patient demographics, referral patterns, and procedure volumes, and may also help with projections for LAAO procedures. Collaboration with clinical teams is crucial, and administrators need to work closely with clinical teams, including interventional cardiologists, electrophysiologists, and cardiovascular surgeons, to understand their patient populations and potential candidates for LAAO procedures. Their insights can also help inform volume projections and resource planning.
- Staying informed about industry trends, technological advancements, and changes in clinical guidelines related to LAAO procedures will help predict future demand for LAAO procedures and anticipate shifts in procedure volumes. Corazon also advocates the use of financial modeling and sensitivity analysis to evaluate different scenarios and assess the impact of potential changes in factors such as procedure volume, reimbursement rates, and costs. The use of data analytics tools and forecasting techniques can help develop projection models for LAAO procedures. Consider

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- factors like growth rates, seasonality, and patient preferences to create realistic volume projections over a specific time. By combining data analysis, market research, collaboration with clinical teams, and industry insights, healthcare administrators can develop accurate volume projections for LAAO procedures. Regular monitoring and adjustment of projections based on real-time data and feedback can help optimize resource allocation and service delivery for LAAO procedures.
- Expertise and Resources: Another crucial consideration is ensuring the organization has the necessary expertise, equipment, and facilities to perform LAAO procedures safely and efficiently. Administrators should verify the CCL is equipped with all the necessary tools, imaging technology, infrastructure, safety standards, and infection control measures. This check should also include ensuring that interventional cardiologists and other healthcare providers have received specialized training courses, proctoring, and hands-on experience with the specific devices used for LAAO, so procedures are performed safely with the best possible outcomes.

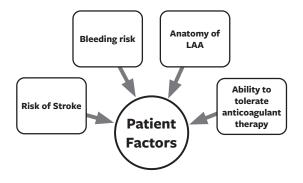
By systematically assessing the financial feasibility of offering LAAO procedures and addressing key considerations related to costs, reimbursement, patient volume, and financial projections, organizations can make informed decisions about implementing LAAO services and optimize the financial outcomes for patients and the organization.

Implementation Considerations

Corazon recommends involving a multidisciplinary team of cardiologists, electrophysiologists, imaging specialists, and nursing staff in the planning and implementation of providing LAAO procedures. Collaboration among team members is essential for successful patient outcomes.

When implementing a new service/procedure in the CCL, several important considerations should be considered to ensure successful and efficient integration. Consider the following key items:

- Clinical Guidelines and Training: Ensure the new procedure/service aligns with clinical guidelines and best practices by developing needed guidelines, policies, and processes that follow recommendations from professional medical societies, such as the American College of Cardiology (ACC), the Society for Cardiovascular Angiography and Interventions (SCAI), the Heart Rhythm Society (HRS), and the American Heart Association (AHA), regarding the use of LAAO procedures for stroke prevention in patients with AF. In addition, ensure that adequate training for the staff, including physicians, nurses, and technologists, takes place to ensure competency in performing the procedure safely and effectively.
- Patient Selection Criteria: Establishing clear criteria for identifying suitable candidates for LAAO procedures should be based on the most recent societal guidelines from professional medical societies (as mentioned above) and should be based on the patient's clinical profile and imaging findings, including the patient's risk of stroke, bleeding risk, anatomy of the left atrial appendage, and ability to tolerate anticoagulation therapy. Corazon recommends the development of standardized protocols for patient evaluation and consent procedures.



Equipment and Technology: Ensure that the CCL equipment is properly calibrated and up to date to meet the specific needs of the procedure.

Implement processes for monitoring the quality and outcomes of LAAO procedures, including tracking for procedural success, complication rates, patient outcomes, and participation in a national registry. Establish safety measures, including infection control practices, radiation safety protocols, and emergency response procedures.

- Staffing and Workflow: Evaluate the impact
 of the new procedure on staffing requirements
 and workflow processes within the CCL.
 Determine the appropriate staffing levels,
 scheduling protocols, and patient flow to
 efficiently accommodate the new service.
- Quality Assurance and Safety Measures: Implement processes for monitoring the quality and outcomes of LAAO procedures, including tracking for procedural success, complication rates, patient outcomes, and participation in a national registry. Establish safety measures, including infection control practices, radiation safety protocols, and emergency response procedures. Engaging in continuous quality improvement efforts optimizes patient care.
- Financial and Reimbursement Considerations: When implementing the LAAO procedure in the CCL, there are several specific financial and reimbursement considerations that healthcare providers should keep in mind. Some key aspects to consider regarding billing, coding, and documentation for LAAO procedures include evaluating the financial implications of introducing the new procedure, including equipment costs, staff training, and potential revenue generation. To avoid denials or under-reimbursement, it is imperative to understand the reimbursement landscape and billing requirements associated with the new service. In addition, adequate documentation is crucial for supporting the medical necessity of LAAO procedures and ensuring appropriate reimbursement. Physicians should document the indication for the procedure, patient selection criteria, procedural details, intra-procedural findings, and post-procedural care in the medical record. Some payers
- may require prior authorization for LAAO procedures to confirm the medical necessity of the procedure; in these cases, providers should be prepared to submit supporting documentation, including clinical indications, imaging studies, and patient history, to obtain prior authorization. Implementing effective revenue cycle management processes will allow organizations to optimize billing, coding, and reimbursement for LAAO procedures. Departments should regularly evaluate billing workflows, claims processing, and reimbursement trends to identify opportunities for improvement and maximize revenue potential. Collaboration with coding and billing staff, ongoing training on coding guidelines, and continuous monitoring of reimbursement trends can help optimize financial outcomes and compliance with regulatory requirements.
- Communication and Marketing: Develop a communication plan to inform stakeholders, including referring physicians, patients, and the community, about the availability of the new service. Organizations should develop a plan to get referrals for the program from outside their hospital. Hospitals should research population statistics from their region to help understand and predict coming trends with aging patients to be sure there are enough potential patients to support a program. Marketing the new procedure effectively will raise awareness and drive patient referrals.

Conclusion

By carefully addressing these items, cath labs can effectively implement new procedures or services while ensuring patient safety, staff proficiency, regulatory compliance, and financial viability. Corazon believes that regular monitoring, feedback

collection, and quality improvement initiatives can help optimize the delivery of the new service over time and encourages accreditation as a way for an organization to ensure regular monitoring.

Atrial fibrillation is a significant risk factor for ischemic stroke, often resulting in fivefold increased stroke risk and twofold increased mortality, and exponentially increases the cost of treatment.⁴ Expanding cardiovascular services offered by your organization can have a meaningful impact on the population and your community as a whole.

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