Medical Coverage Policy

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Atrial Fibrillation: Nonpharmacological Treatments

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Overview

This Coverage Policy addresses nonpharmacological treatments for atrial fibrillation including catheter ablation of the pulmonary veins surgical and percutaneous transcatheter closure of the left atrial appendage and surgical and minimally invasive maze procedures.

Coverage Policy

CATHETER ABLATION

Cardiac catheter ablation with pulmonary vein isolation (Current Procedural Terminology [CPT®] codes 93656, 93657) is considered medically necessary for ANY of the following indications:

- Symptomatic atrial fibrillation (paroxysmal or persistent) AND antiarrhythmic drugs have been ineffective, contraindicated, not tolerated or not preferred
- Symptomatic atrial fibrillation (e.g., palpitations, chest pain, dyspnea) associated with heart failure and reduced ejection fraction (HFrEF) of ≤ 40%.
- An athlete* who develops atrial fibrillation with or without symptoms
  *high-volume endurance athleticism, defined as exercise of >45 metabolic equivalent-hours per week
- Individual with or without symptoms with pulmonary hypertension (PH) with pulmonary vascular disease and atrial fibrillation or atrial flutter

Repeat cardiac catheter ablation is considered medically necessary for an individual with recurrent symptomatic atrial fibrillation (American College of Cardiology Class 1 recommendation).

Cardiac catheter ablation for ANY other indication including asymptomatic atrial fibrillation (except as discussed above) is considered not medically necessary.

Vein of Marshall alcohol ablation (VOM ethanol infusion) (CPT® code 93799) for the treatment of paroxysmal/persistent atrial fibrillation is considered not medically necessary.

Use of an active esophageal cooling device during cardiac catheter ablation (HCPCS C1889) is considered experimental, investigational or unproven.

PERCUTANEOUS APPROACHES TO OCCLUDE THE LEFT ATRIAL APPENDAGE (LAA)

Percutaneous transcatheter closure of the left atrial appendage (CPT® code 33340) for non-valvular atrial fibrillation using a U.S. Food and Drug Administration (FDA) approved device is considered medically necessary for the prevention of stroke in an individual with a moderate to high risk of stroke (CHA_2DS_2-VASc score ≥2*), and a contraindication to long-term oral anticoagulation due to a nonreversible cause (e.g., arteriovenous malformation (AVM) in intestine or brain that is not treatable, recurrent duodenal ulcer).

> *CHA_2DS_2-VASc is a clinical risk score for prediction of stroke and systemic embolism: Congestive heart failure, hypertension, age greater than or equal to 65, diabetes, stroke/transient ischemia attack/thromboembolism, vascular disease, sex category.

Percutaneous transcatheter closure of the left atrial appendage for ANY other indication including hypertrophic cardiomyopathy is considered NOT medically necessary.

CARDIAC SURGERY—LAA EXCLUSION/EXCISION

Surgical closure of the left atrial appendage (CPT® code 33268, e.g., excision, isolation via stapling, oversewing, ligation, plication, clip) in conjunction with other cardiac surgical procedures using a U.S. Food and Drug Administration (FDA) approved device is considered medically necessary for the prevention of stroke.

Closure of the left atrial appendage not performed in conjunction with an open cardiac surgical procedure (CPT® codes 33267, 33269) is considered not medically necessary.

The closure of a peridevice leak (PDL) after a left atrial appendage occlusion (CPT® code 33999) is considered experimental, investigational or unproven.

SURGICAL ABLATION

Surgical Maze or modified Maze procedure with cardiopulmonary bypass (CPT® codes 33256, 33257, 33259) is considered medically necessary in an individual with atrial fibrillation who is undergoing cardiac surgery.

Surgical Maze or modified Maze procedure without cardiopulmonary bypass (CPT® codes 33258) is considered medically necessary in an individual with atrial fibrillation who is undergoing cardiac surgery.

Surgical Maze or modified Maze procedure including endoscopic Maze as a part of a hybrid convergent procedure without cardiopulmonary bypass when concomitant cardiac surgery is not performed (CPT® codes 33254, 33255, 33265, 33266) is considered experimental, investigational or unproven for any indication including the treatment of atrial fibrillation.

Health Equity Considerations

Health equity is the highest level of health for all people; health inequity is the avoidable difference in health status or distribution of health resources due to the social conditions in which people are born, grow, live, work, and age.

Social determinants of health are the conditions in the environment that affect a wide range of health, functioning, and quality of life outcomes and risks. Examples include safe housing,

transportation, and neighborhoods; racism, discrimination and violence; education, job opportunities and income; access to nutritious foods and physical activity opportunities; access to clean air and water; and language and literacy skills.

See General Background for statistics.

General Background

Atrial Fibrillation (also known as 'AFib' or abbreviated AF) is the most common heart rhythm disorder or arrhythmia. Many, but not all, people with AF say they can feel their heart racing, fluttering, or skipping beats. Other atrial arrhythmias are often encountered in individuals with AF. A major concern with AF is that it allows blood clots to form in the heart. These clots can then travel throughout the body and block blood flow. AF prevalence in the United States was estimated to be 5.2 million in 2010, with an expectation to rise to 12.1 million in 2030. Overall lifetime risk is about 30% to 40% in White individuals, about 20% in African American individuals, and about 15% in Chinese individuals. AF is associated with a 1.5- to 2-fold increased risk of death. Studies suggest that the mortality risk may be higher in women than in men. AF is also associated with increased risk stroke, cognitive impairment or dementia, myocardial infarction (MI), sudden cardiac death, heart failure (HF), chronic kidney disease (CKD), peripheral artery disease (PAD).

The foundation of optimal AF management is the treatment of risk factors and implementing lifestyle changes to decrease the likelihood of developing AF. Once AF develops, patient care should focus on assessing the risk of stroke and implementing any necessary treatment, continued optimization of all modifiable risk factors, and managing potential symptoms of AF, with an initial focus on evaluating and minimizing AF burden.

Definitions:

Atrial Fibrillation	a supraventricular tachyarrhythmia with uncoordinated atrial activation and ineffective atrial contraction.
Subclinical AF	refers to this arrhythmia identified in individuals who do not have symptoms attributable to AF and in whom there are no previous ECGs documenting AF.
AF burden	encompasses both frequency and duration and refers to the amount of AF that an individual has.
Paroxysmal AF	intermittent and terminates within ≤7 days of onset.
Persistent AF	continuous and sustains for >7 days and requires intervention. Of note, patients with persistent AF who, with therapy, become paroxysmal should still be defined as persistent as this reflects their original pattern.
Long-standing persistent AF	AF that is continuous for >12 months in duration.
Permanent AF	when the patient and clinician make a joint decision to stop further attempts to restore and/or maintain sinus rhythm Acceptance of AF represents a therapeutic decision and does not represent an inherent pathophysiological attribute of AF

Stages of Atrial Fibrillation:

1	At risk for AF Presence of modifiable (e.g., obesity) and nonmodifiable (genetics) risk factors
2	Pre-AF

	Evidence of structural or electrical findings further predisposing an individual to AF (e.g., atrial enlargement, frequent atrial ectopy, short bursts of atrial tachycardia)
3A	Paroxysmal AF
3B	Persistent AF
3C	Long-standing persistent AF
3D	Successful AF ablation Freedom from AF after percutaneous or surgical intervention to eliminate AF
4	Permanent AF

CATHETER ABLATION (CPT® codes 93656, 93657)

Before ablation surgery, electrical mapping of the heart using an electrically sensitive catheter to map the origins of "extra" electrical activity throughout the heart is conducted. The map identifies which areas of the heart are creating problematic electric signals that interfere with the proper rhythm. A catheter is then inserted into a blood vessel and guided to the heart. The doctor carefully destroys malfunctioning tissue using the catheter to deliver energy (such as radiofrequency, laser or cryotherapy) to scar the problematic areas. The goal is the scarred areas will no longer send abnormal signals.

Catheter Ablation – U.S. Food and Drug Administration (FDA): Numerous ablation catheters have received FDA approval through the premarket application (PMA) process for treatment of arrhythmias. Some examples include Arctic Front® CryoCatheter System (Medtronic CryoCath), HeartLight® Endoscopic Ablation System (CardioFocus, Inc.), PulseSelect™ Pulsed Field Ablation (PFA) system (Medtronic, Inc), and FARAPULSE™ Pulsed Field Ablation System (FARAPULSE, Inc.).

PulseSelect™ Pulsed Field Ablation (PFA) system (Medtronic, Inc), received FDA PMA approval on 12/13/2023 (P230017). The PulseSelect™ PFA loop catheter is indicated for use in cardiac electrophysiological mapping (stimulation and recording) and for treatment of drug refractory, recurrent, symptomatic paroxysmal atrial fibrillation or persistent atrial fibrillation (episode duration less than 1 year) when used in conjunction with the PulseSelect™ PFA system.

FARAPULSE™ Pulsed Field Ablation System (FARAPULSE, Inc.) received FDA PMA approval on 1/30/2024 (P230030). The FARAWAVE Catheter is indicated for the isolation of pulmonary veins in the treatment of drug-refractory, recurrent, symptomatic paroxysmal atrial fibrillation (PAF).

Catheter Ablation – Professional Societies/Organizations: The American College of Cardiology/ American Heart Association (ACC/AHA) 2024 Guideline for the Diagnosis and Management of Atrial Fibrillation (ACC/Joglar, et al., 2024) lists the following recommendations regarding catheter ablation:

*(Class of Recommendation [COR] and Level of Evidence [LOE], See Appendix)	**COR***	**LOE***
8.1. Goals of Therapy With Rhythm Control		
In patients with reduced LV function and persistent (or high burden) AF, a trial of rhythm control should be recommended to evaluate whether AF is contributing to the reduced LV function.	I	B-R

*(Class of Recommendation [COR] and Level of Evidence [LOE], See Appendix)	**COR***	**LOE***
In patients with symptomatic AF, rhythm control can be useful to improve symptoms.	IIa	B-R
In patients with a recent diagnosis of AF (<1 year), rhythm control can be useful to reduce hospitalizations, stroke, and mortality.	IIa	B-R
In patients with AF and HF, rhythm control can be useful for improving symptoms and improving outcomes, such as mortality and hospitalizations for HF and ischemia.	IIa	B-R
In patients with AF, rhythm-control strategies can be useful to reduce the likelihood of AF progression.	IIa	B-NR
In patients with AF where symptoms associated with AF are uncertain, a trial of rhythm control (eg, cardioversion or pharmacological therapy) may be useful to determine what if any symptoms are attributable to AF.	IIb	C-LD
In patients with AF, rhythm-control strategies may be useful to reduce the likelihood of development of dementia or worsening cardiac structural abnormalities.	IIb	B-NR
8.4. AF Catheter Ablation		
In patients with symptomatic AF in whom antiarrhythmic drugs have been ineffective, contraindicated, not tolerated or not preferred, and continued rhythm control is desired, catheter ablation is useful to improve symptoms.	I	A
In selected patients (generally younger with few comorbidities) with symptomatic paroxysmal AF in whom rhythm control is desired, catheter ablation is useful as first-line therapy to improve symptoms and reduce progression to persistent AF.	I	A
In patients with symptomatic or clinically significant atrial flutter (AFL), catheter ablation is useful for improving symptoms.	I	A
In patients who are undergoing ablation for AF, ablation of additional clinically significant supraventricular arrhythmias can be useful to reduce the likelihood of future arrhythmia.	IIa	B-NR
In patients (other than younger with few comorbidities) with symptomatic paroxysmal or persistent AF who are being managed with a rhythm-control strategy, catheter ablation as first-line therapy can be useful to improve symptoms.	IIa	B-R
In selected* patients with asymptomatic or minimally symptomatic AF, catheter ablation may be useful for reducing progression of AF and its associated complications. *Younger patients with few comorbidities and a moderate to high burden of AF or persistent AF and AFL.	IIb	B-NR
8.4.2. Techniques and Technologies for AF Catheter Ablation		
In patients undergoing ablation for AF, pulmonary vein isolation (PVI) is recommended as the primary lesion set for all patients unless a different specific trigger is identified.	I	A
In patients undergoing ablation for AF, the value of other endpoints beyond PVI such as non-inducibility and ablation of additional anatomic ablation targets (eg, posterior wall sites, low voltage areas, complex fractionated electrograms, rotors) is uncertain.	IIb	B-R
8.4.3. Management of Recurrent AF After Catheter Ablation		

*(Class of Recommendation [COR] and Level of Evidence [LOE], See Appendix)	**COR***	**LOE***
In patients with recurrent symptomatic AF after catheter ablation, repeat catheter ablation or antiarrhythmic drug therapy is useful to improve symptoms and freedom from AF.	I	B-NR
9.2. Management of AF in Patients With HF		
In patients who present with a new diagnosis of HFrEF and AF, arrhythmia-induced cardiomyopathy should be suspected, and an early and aggressive approach to AF rhythm control is recommended.	I	B-NR
In appropriate patients with AF and HFrEF who are on guideline-directed management and therapy (GDMT), and with reasonable expectation of procedural benefit, catheter ablation is beneficial to improve symptoms, quality of life (QOL), ventricular function, and cardiovascular outcomes.	I	A
In appropriate patients with symptomatic AF and heart failure with reduced ejection fraction (HFpEF) with reasonable expectation of benefit, catheter ablation can be useful to improve symptoms and improve QOL.	IIa	B-NR
In patients with suspected AF-induced cardiomyopathy or refractory HF symptoms undergoing pharmacological rate-control therapy for AF, a stricter rate-control strategy (target heart rate <80 bpm at rest and <110 bpm during moderate exercise) may be reasonable.	IIb	B-NR
10.1. Management of Early Onset AF, Including Genetic Testing		
In patients with an onset of unexplained AF before 30 years of age, electrophysiological study to evaluate and treat reentrant supraventricular tachyarrhythmias with a targeted ablation may be reasonable because of the high prevalence of reentrant arrhythmias in this group.	IIb	B-NR
10.2. Athletes		
In athletes who develop AF, catheter ablation with pulmonary vein isolation (PVI) is a reasonable strategy for rhythm control because of its effectiveness and low risk of detrimental effect on exercise capacity.	IIa	B-NR
10.6. Wolff-Parkinson-White (WPW) and Preexcitation Syndromes		
For patients with AF with rapid anterograde conduction (preexcited AF), catheter ablation of accessory pathways (APs) is recommended.	I	B-NR
10.8. Adult Congenital Heart Disease (ACHD)		
In adults with congenital heart disease and symptomatic or hemodynamically significant paroxysmal or persistent AF, an initial strategy of rhythm control is recommended regardless of lesion severity as AF in this population is often poorly tolerated.	I	C-LD
In symptomatic patients with simple congenital heart disease with antiarrhythmic drug–refractory AF, it is reasonable to choose ablation over long-term antiarrhythmic therapies.	IIa	B-NR
In adults with congenital heart disease with AF undergoing pulmonary vein isolation (PVI), it may be reasonable to include an ablative strategy in the right atrium directed at reentrant arrhythmia secondary to atriotomy scars and the cavotricuspid isthmus (CTI).	IIb	C-LD
10.12. Pulmonary Disease		

*(Class of Recommendation [COR] and Level of Evidence [LOE], See Appendix)	**COR***	**LOE***
In patients with pulmonary hypertension (PH) with pulmonary vascular disease and AF or atrial flutter (AFL), a rhythm control strategy is reasonable to improve functional status and potentially prolong survival.	IIa	B-NR
10.15. CKD and Kidney Failure		
Data on the management of AF in patients with CKD is limited because the major trials of rate control, rhythm control, and catheter ablation have generally not reported eGFR or CKD as a baseline variable or excluded such patients. Antiarrhythmic drug doses are adjusted based on pharmacokinetic data and clinical experience, with amiodarone being the only drug that does not require dose adjustment in patients with CKD or those receiving dialysis. Catheter ablation is feasible, although particular attention must be paid to fluid balance when using irrigated radiofrequency catheters.	n/a	n/a
Future Research Needs		
Standardization of ablation procedures: Great practice variation exists on how AF ablation procedures are performed, either as first or repeat procedures. Large registries and more data are required to better define standards of care in this field. Candidates for ablation: We must better identify clinical markers to better identify when catheter ablation is unlikely to benefit patients and define specific criteria for candidacy for first time and repeat procedures (ACC/Joglar, et al., 2024).	n/a	n/a

The 2024 AHA/ACC Guideline for the Diagnosis and Treatment of Patients With Hypertrophic Cardiomyopathy (HCM) (Ommen, et al., 2024) includes recommendations on AF

*(Class of Recommendation [COR] and Level of Evidence [LOE], See Appendix)	**COR***	**LOE***
Recommendations on AF 8.4 Management of Patients With HCM and AF		
6. In patients with HCM and symptomatic AF, as part of a AF rhythm control strategy, catheter ablation for AF can be effective when drug therapy is ineffective, contraindicated, or not the patient's preference	IIa	B-NR
7. In patients with HCM and AF who require surgical myectomy, concomitant surgical AF ablation procedure can be beneficial for AF rhythm control	IIa	B-NR

In 2022, the AHA/ACC/Heart Failure Society of America (HFSA) updated the Guideline for the Management of Heart Failure recommended that for patients with HF and symptoms caused by AF, AF ablation is reasonable to improve symptoms and QOL (Heidenreich, et al. 2022).

Catheter Ablation – Literature Review: Catheter ablation has become an established therapy for AF because of multiple RCTs and evidence from large registries and continues to evolve as new technologies are developed. Previous professional society documents have provided different recommendations for catheter ablation dependent on whether AF was persistent or paroxysmal. More recent information has shown that ablation for AF is more effective than antiarrhythmic drugs for both persistent and paroxysmal AF (Monahan, et al., 2022; Kuck, et al., 2021; Nyong, et al., 2016). Although RCTs have mainly used younger patients (<70 years of age) who also experience the largest benefits, observational studies have reported improvement in QOL with catheter ablation in older patients. A recent meta-analysis of six RCTs found that strategies that included pulmonary vein isolation (PVI) were associated with a 50% reduction in the development of recurrent AF when compared with strategies that did not include PVI (Sau, et al., 2019) (ACC/Joglar, et al., 2024).

Vein of Marshall alcohol ablation (VOM ethanol infusion) (CPT® code 93799): The vein of Marshall is a remnant of the left superior vena cava and has been associated with multiple arrhythmias (e.g., atrial arrhythmias, ventricular arrhythmias, and accessory pathways). VOM can control the electrical potential of the atrial tissue and contribute to atrial fibrillation (AF). Vein of Marshall (VOM) ethanol infusion during atrial fibrillation ablation is being evaluated as a treatment for persistent atrial fibrillation. It is proposed that ethanol infusion into the VOM increases the chances of remaining free of atrial fibrillation. There is currently a paucity of evidence in the published peer-reviewed medical literature evaluating the safety and effectiveness of VOM ethanol infusion during a catheter ablation for the treatment of persistent atrial fibrillation. The evidence evaluating VOM ethanol infusion during a catheter ablation for the treatment of persistent atrial fibrillation is primarily in the form of a randomized controlled trial, retrospective reviews, prospective case series, observational studies, and review articles (He, et al., 2022; Lai, et al., 2021; Valderrábano, et al., 2020; Liu, et al., 2019). Further studies in large, diverse populations with long-term follow-up are needed to evaluate efficacy, optimize protocols and outcomes.

Valderrábano et al. (2020) conducted a randomized controlled trial that assessed if adding vein of Marshall ethanol infusion to the catheter ablation procedure reduced the recurrence of atrial fibrillation in patients with persistent atrial fibrillation (VENUS trial). Adults aged 18–85 years with symptomatic persistent AF (sustained AF lasting > 7days) refractory to at least one antiarrhythmic agent were included in the study. No health disparities were identified by the investigators. Patients (n=343) were randomly assigned in a 1:1.15 ratio to accommodate for 15% technical vein of Marshall ethanol infusion failures to catheter ablation alone (n=158) or catheter ablation combined with vein of Marshall ethanol infusion (n=185). The primary outcome was freedom from AF or atrial tachycardia for longer than 30 seconds after a single procedure, without antiarrhythmic drugs, at both six and 12 months. There were 12 secondary outcomes, included that measured AF burden, freedom from AF after multiple procedures, perimitral block, and others. Clinical assessments and 12-lead electrocardiograms were obtained at baseline and at one, three, six, nine and 12 months after the initial ablation. Additionally, patients underwent continuous one month monitoring (MediLynx) at six and 12 months after ablation. Of the 343 randomized patients, 316 (92.1%) completed the trial and adherence to the 30-day event monitor at six and 12 months was 85.1% and 83.3%, respectively. Catheter ablation with vein of Marshall ethanol infusion, compared with catheter ablation alone, resulted in freedom from atrial fibrillation or prolonged atrial tachycardia in 49% vs 38% at both six and 12 months, a difference that was statistically significant (p=0.04). Of the 12 secondary outcomes, nine were not significantly different, but AF burden (p=0.01), freedom from AF after multiple procedures (p=0.04), and success achieving perimitral block (p<0.001) were significantly improved in vein of Marshall–treated patients. Adverse events were similar between groups. The authors noted several limitations which include potential investigator bias in the catheter ablation group, the vein of Marshall ethanol infusion procedure was not completed in all patients randomized to it, adherence to monitoring was incomplete and the primary outcome could not be ascertained in 27 patients

because of lacking monitoring data and ten patients had repeat procedures performed during the blanking period. Additional limitations include the small patient population, short term follow-up and included over 90% of white patients and the results may not be applicable to other races or ethnic groups. Authors concluded that among patients with persistent AF, addition of vein of Marshall ethanol infusion to catheter ablation, compared with catheter ablation alone, increased the likelihood of remaining free of AF or atrial tachycardia at six and 12 months. However, further research is needed to assess longer-term efficacy.

PERCUTANEOUS TRANSCATHETER CLOSURE OF THE LEFT ATRIAL APPENDAGE (LAA) (CPT® Code 33340)

Three main approaches to stroke prevention in AF are: elimination of AF; prevention of clot formation with antiplatelet or anticoagulant agents; and physical elimination of the left atrial appendage (LAA) which excludes the site of clot formation. Among patients with non-valvular AF, most of the thrombus material is located within or involves the LAA. Approximately 90% of left atrial thrombi form in the LAA. Most patients with AF receive anticoagulant therapy to reduce the risk of systemic embolization. There are varying degrees of bleeding risk associated with anticoagulation and not all individuals are candidates for this therapy. The optimal approach to reducing the risk of embolization in patients for whom long-term anticoagulation is indicated, but who are unable to take it, is unclear. Percutaneous approaches, often referred to as LAA exclusion procedures, that mechanically prevent embolization of LAA thrombi have been developed. At present, there are two categories of percutaneous LAA occlusion devices: endocardially and epicardially delivered. In addition, LAA exclusion at the time of surgery has been proposed for some patients undergoing cardiac surgery for reasons such as valve replacement or repair or coronary artery bypass graft surgery.

Several studies have reported that women had higher rates of in-hospital adverse events following LAAC than men did. It is recommended that further research is warranted to identify sex-specific, racial/ethnic, and socioeconomic pathways during the patient selection process to minimize complications in patients undergoing LAAC (Darden, et al., 2021; Sanjoy, et al., 2021).

Percutaneous closure of the LAA – U.S. Food and Drug Administration (FDA): FDA-approved LAA closure devices include the Watchman™ Left Atrial Appendage Closure Device, Watchman FLX™ (P130013, 03/13/2015) including WATCHMAN FLX™ Pro Left Atrial Appendage Closure (LAAC) Device (Sept 2023), and the Amplatzer™ Amulet™ Left Atrial Appendage Occluder (P200049, 08/14/2021).

Percutaneous closure of the LAA – Professional Societies/Organizations: The ACC/AHA 2024 Guideline for the Diagnosis and Management of Atrial Fibrillation (ACC/Joglar, et al., 2024) lists the following recommendations regarding percutaneous left atrial appendage occlusion (pLAAO):

*(Class of Recommendation [COR] and Level of Evidence [LOE], See Appendix)	**COR***	**LOE***
6.5.1. Percutaneous Approaches to Occlude the left atrial appendage (LAA)		
In patients with Atrial Fibrillation (AF), a moderate to high risk of stroke (CHA2DS2-VASc score ≥2), and a contraindication to long-term oral anticoagulation due to a nonreversible cause, percutaneous LAA occlusion (pLAAO) is reasonable.	IIa	B-NR
In patients with AF and a moderate to high risk of stroke and a high risk of major bleeding on oral anticoagulation, pLAAO may be a reasonable	IIb	B-R

*(Class of Recommendation [COR] and Level of Evidence [LOE], See Appendix)	**COR***	**LOE***
alternative to oral anticoagulation based on patient preference, with careful consideration of procedural risk and with the understanding that the evidence for oral anticoagulation is more extensive.		
6.6.1. Management of Patients With AF and ICH		
In patients with AF and conditions associated with high risk of recurrent intracranial hemorrhage (ICH) (eg, cerebral amyloid angiopathy) anticoagulation-sparing strategies (eg, LAAO) may be considered to reduce the risk of recurrent hemorrhage (ACC/Joglar, et al., 2024).	IIb	B-NR

Society for Cardiovascular Angiography & Interventions (SCAI)/ Heart Rhythm Society (HRS): Recommendations from the SCAI/HRS Expert Consensus Statement on transcatheter left atrial appendage closure (Saw, et al., 2023) include but are not limited to the following:

- Transcatheter left atrial appendage closure (LAAC) is appropriate for patients with nonvalvular atrial fibrillation with high thromboembolic risk who are not suited for long-term oral anticoagulation and who have adequate life expectancy (minimum >1 year) and quality of life to benefit from LAAC.
- Routine closure of iatrogenic atrial septal defects associated with LAAC should not be performed.
- The clinical impact and management of peridevice leaks are not fully understood, and all efforts should be made to minimize such leaks at the time of implantation.
- Combined procedures with LAAC (eg, structural interventions, pulmonary vein isolation) are not routinely recommended, as data are pending from ongoing randomized controlled trials.

Percutaneous closure of the LAA – Literature Review: pLAAO devices are designed to prevent embolization of LAA thrombi and potentially obviate the need for oral anticoagulant (OAC) for stroke risk reduction. RCTs have demonstrated pLAAO to be noninferior to warfarin and direct OACs for stroke and systemic embolism with a reduced risk of major bleeding.
The Watchman device received FDA approval based upon the results of PROTECT AF (Reddy, et al., 2014) and PREVAIL (Holmes, et al., 2014; Reddy, et al., 2017) randomized controlled trials. The Amplatzer™ Amulet™ Left Atrial Appendage Occluder received FDA approval based upon the results of The AMPLATZER Amulet LAA Occluder Trial (Amulet IDE) (Lakkireddy, et al., 2021; Lakkireddy, et al., 2023).

CARDIAC SURGERY—LAA EXCLUSION/EXCISION (Surgical closure of the left atrial appendage CPT® code 33268)

In patients with AF undergoing cardiac surgery, concomitant surgical LAA closure offers an option for stroke prevention strategy. A variety of surgical approaches to LAA occlusion have been proposed, including suture exclusion (via endocardial or epicardial ligation), suture excision, stapler exclusion/excision with or without suture reinforcement, snares/suture loops, epicardial exclusion clips, and others still currently under development. All of these techniques have the primary goal of complete exclusion of the LAA in order to prevent thrombus formation.

Cardiac Surgery—LAA Exclusion/Excision – U.S. Food and Drug Administration (FDA):

FDA-approved LAA closure devices, approved for use under direct visualization in conjunction with other open cardiac surgical procedures, includes the AtriClip LAA Exclusion System (K093679, June 2010).

The Syntheon Left Atrial Appendage (LAA) Exclusion System (Syntheon, LLC) received 510(k) approval on October 28, 2022 (K220305, Product Code: PZX). The Syntheon LAA Exclusion System is indicated for the exclusion of the heart's left atrial appendage, performed under direct visualization and in conjunction with other cardiac surgical procedures. According to the Medtronic website, Medtronic completed the acquisition of Syntheon LLC in August 2023; the Penditure™ LAA Exclusion System received a 510k clearance in August 2023; the Penditure™ system is commercially available in the USA on a limited basis at this time. However, 'Penditure' is not indicated as approved on the FDA website.

Cardiac Surgery—LAA Exclusion/Excision – Professional Societies/Organizations: The ACC/AHA 2024 Guideline for the Diagnosis and Management of Atrial Fibrillation (ACC/Joglar, et al., 2024) lists the following recommendations regarding concomitant surgical LAA closure in individuals with AF undergoing cardiac surgery:

*(Class of Recommendation [COR] and Level of Evidence [LOE], See Appendix)	**COR***	**LOE***
6.5.2. Cardiac Surgery—LAA Exclusion/Excision		
In patients with AF undergoing cardiac surgery with a CHA_2DS_2-VASc* score ≥2 or equivalent stroke risk, surgical LAA exclusion, in addition to continued anticoagulation, is indicated to reduce the risk of stroke and systemic embolism. *congestive heart failure, hypertension, age ≥75 years (doubled), diabetes mellitus, prior stroke or transient ischemic attack or thromboembolism (doubled), vascular disease, age 65 to 74 years, sex category	I	A
In patients with AF undergoing cardiac surgery and LAA exclusion, a surgical technique resulting in absence of flow across the suture line and a stump of <1 cm as determined by intraoperative transesophageal echocardiography should be used.	I	A
In patients with AF undergoing cardiac surgery with CHA2DS2-VASc score ≥2 or equivalent stroke risk, the benefit of surgical LAA exclusion in the absence of continued anticoagulation to reduce the risk of stroke and systemic embolism is uncertain.	IIb	A
6.6.1. Management of Patients With AF and ICH		
In patients with AF and conditions associated with high risk of recurrent intracranial hemorrhage (ICH) (eg, cerebral amyloid angiopathy) anticoagulation-sparing strategies (eg, LAAO) may be considered to reduce the risk of recurrent hemorrhage (ACC/Joglar, et al., 2024).	IIb	B-NR

Recommendations from the SCAI/HRS Expert Consensus Statement on transcatheter left atrial appendage closure (Saw, et al., 2023) include but are not limited to the following:

- Transcatheter left atrial appendage closure (LAAC) is appropriate for patients with nonvalvular atrial fibrillation with high thromboembolic risk who are not suited for long-

term oral anticoagulation and who have adequate life expectancy (minimum >1 year) and quality of life to benefit from LAAC.
- Routine closure of iatrogenic atrial septal defects associated with LAAC should not be performed.
- The clinical impact and management of peridevice leaks are not fully understood, and all efforts should be made to minimize such leaks at the time of implantation. Combined procedures with LAAC (eg, structural interventions, pulmonary vein isolation) are not routinely recommended, as data are pending from ongoing randomized controlled trials

Cardiac Surgery—LAA Exclusion/Excision – Literature Review: The FDA approval of the AtriClip device was based on the Exclusion of the Left Atrial Appendage with the AtriClip LAA Exclusion Device in Patients Undergoing Concomitant Cardiac Surgery (EXCLUDE) clinical trial (Ailawadi, et al., 2011, NCT00779857). Published evidence supports a benefit of S-LAAO in patients with AF who undergo coronary artery bypass graft surgery (CABG) or valve surgeries (Gerdisch, et al., 2022; Whitlock, et al., 2021; Martín Gutiérrez, et al., 2020; ACC/Joglar, et al., 2024).

Closure of the left atrial appendage NOT performed in conjunction with an open cardiac surgical procedure (CPT® codes 33267, 33269): Stand-alone surgical LAA exclusion is being evaluated for patients with atrial fibrillation at increased risk of stroke who are not good candidates for oral anticoagulation. The evidence evaluating stand-alone surgical LAA exclusion is primarily in the form of retrospective reviews, prospective case series, observational studies, and review articles (Cartledge, et al., 2022; Wang, et al., 2021; Branzoli, et al., 2020; Franciulli, et al., 2020). In general, these studies have limitations such as small sample sizes and short-term follow-up that limit the generalizability of their results.

Wang et al. (2021) conducted a prospective cohort study that assessed the safety and efficacy of minimally invasive thoracoscopic left atrial appendage occlusion compared to transcatheter left atrial appendage closure for stroke prevention in recurrent nonvalvular atrial fibrillation patients after radiofrequency ablation. Adults (n=209) age ≥ 18 years with recurrent atrial fibrillation after radiofrequency ablation and CHADS2 score ≥ 2 were included in the study. No health disparities were identified by the investigators. Patients were placed into two groups, the thoracoscopic LAA occlusion group (n=138) and the transcatheter LAA closure group (n=71). The thoracoscopic LAA group had the atrial appendages sutured with a modern stapler and the transcatheter LAA closure group received the WATCHMAN device. Patients were followed up by telephone or at the outpatient clinic at 1 week/45 days/3 months/6 months/12 months/twice annually after one year. Neurologic examinations were performed 12 months/once annually after one year. The efficacy outcomes measured the composite endpoint for stroke/SE and death and the composite endpoint for events from the 3rd month after surgery to the end of follow-up. Additionally, safety was measured using operation-related stroke and the differences in complications between the two groups. The study reported that the length of hospital stay in thoracoscopic LAA occlusion group was significantly longer than that in transcatheter LAA closure group ($p<0.001$). The two groups had similar nonsignificant results regarding the efficacy endpoints and the incidence of TIA/stroke ($p=0.559$; $p=0.496$, respectively). The incidence of bleeding in the thoracoscopic LAA occlusion group was significantly lower than that in the intervention group ($p=0.022$). The incidence of operative complications was 3/138 (2.17%) in thoracoscopic LAA occlusion group and 1/71 (1.41%) in transcatheter LAA closure group. Author noted limitations included the single-center study design and the type of local treatment to the LAA was chosen by the patient with a full explanation from the physician. Additional limitations included the small patient population, short term follow-up and the population only included patients in China and the results may not be applicable to other races or ethnic groups. The authors concluded that the groups had similar effects in preventing stroke. Thoracoscopic LAA occlusion has the advantage of low risk of

bleeding, but it is accompanied by longer hospital stays. Randomized controlled studies with large patient populations and long-term follow-up are needed.

Branzoli et al. (2020) conducted a prospective study that evaluated the safety and effectiveness of a stand-alone thoracoscopic exclusion of the LAA using an epicardial clip for stroke prevention in patients with permanent AF with an absolute contraindication to OAC. Patients (n=45) with non-valvular atrial fibrillation (NVAF) and CHA2DS2-VASc of 6.5 ± 1.1 with contraindications to long-term OAC or at high risk of life-threatening bleeding if on antiplatelet therapy (APT) with HAS-BLED mean 4.9 ± 0.9 were included in the study. No health disparities were identified by the investigators. All patients were implanted with an LAA epicardial clip, guided by preoperative computed tomography (CT) and intraoperative transesophageal echocardiography (TEE). The thoracoscopic access was evaluated at 10 days and clinical evaluations were scheduled at two months, six months, and yearly thereafter, including electrocardiogram, laboratory workout, and physical examination. The Questionnaire for Verifying Stroke-Free Status (QVSFS) was used at each scheduled visit and the latest follow-up as a validated screening tool to identify the occurrence of neurological events occurrence. Clinical and CT/TEE follow-up was complete for all 45 patients and ranged from 2–34 months (mean follow-up period: 16.4 ± 9.1months). There were not any procedure-related complications and intraprocedural transesophageal echocardiography (TEE) showed complete LAA occlusion in all patients. At a mean follow-up of 16.4 ± 9.1 months (range, 2–34), with all patients off oral anticoagulation (OAC), novel oral anticoagulation (NOAC) or antiplatelet therapy (APT), no ischemic stroke or hemorrhagic complications occurred. Computed tomography or TEE at follow-up demonstrated a correct LAA occlusion in all patients. Author noted limitations included the small patient population and limited follow-up. The authors concluded that thoracoscopic epicardial closure of the LAA with the AtriClip PRO2 device is a potentially safe and efficient treatment for stroke prevention in patients with NVAF contraindicated for anticoagulant therapy or APT. However, the effect of the therapy with regard to the reduction of ischemic stroke and hemorrhagic complications in the long-term should be evaluated. Further studies in large, diverse populations with long-term follow-up are needed to evaluate efficacy, optimize protocols and outcomes.

The efficacy and safety of stand-alone thoracoscopic LAA appendectomy has not been established. Randomized controlled trials with larger patient populations and long-term follow-up are needed.

Closure of a peridevice leak (PDL) after a left atrial appendage occlusion (CPT® code 33999): The safety and efficacy of left atrial appendage occlusion using FDA approved devices has been established, however a complication that can occur at the time of implantation or during follow-up is a peridevice leak. The clinical consequences of PDL are unknown.

The FDA label for post-procedure information issued on July 21, 2022 (P130013/S035) stated that "cessation of oral anticoagulant therapy is at physician discretion provided that any leak demonstrated is ≤ 5 mm. If adequate seal is not demonstrated, subsequent OAC therapy cessation decisions are contingent on demonstrating leak is ≤ 5 mm." Additionally, the FDA recommended that TEE imaging at 45 days and at 12 months be performed to assess the WATCHMAN FLX Device to confirm absence of intra-cardiac thrombus. To assess for leakage, a color Doppler assessment should be performed that includes the device/LAA border and to measure any residual leak around the device into the LAA. If there is evidence of leak > 5 mm, the FDA recommended to continue or restart anticoagulation therapy.

Recommendations from the SCAI/HRS expert consensus statement on transcatheter left atrial appendage closure (Saw, et al., 2023) include a statement that referenced peridevice leaks (PDLs) noting that the clinical impact and management of PDLs are not fully understood and at the time of implantation all efforts should be made to minimize leaks (Saw, et al., 2023).

Studies addressing the significance of PDL on clinical outcomes primarily include retrospective studies with inconsistent results. Closure of the PDL using coils, plugs, and radiofrequency ablation techniques is being investigated, however there is insufficient evidence in the peer-reviewed literature that correcting the leak leads to better clinical outcomes opposed to oral anticoagulant (OAC) or observation (Alkhouli, et al., 2022; Dukkipati, et al., 2022; Della Rocca, et al., 2022; Piayda, et al., 2021; Sleiman, et al., 2021; Della Rocca, et al., 2020). Future studies should address whether closure of persistent peridevice leaks reduces the risk of subsequent ischemic stroke and improves clinical outcomes when compared to OAC or observation.

Ledesma et al. (2021) analyzed the post-approval outcomes following left atrial appendage closure with the watchman device to determine the frequency and timing of adverse events. Within the 2,257 reports there were 3,652 adverse events reported. The study reported that the incidence of peridevice leaks was 0.2% (n=83). The size of the reported leaks ranged from 0.5 mm to 9.2 mm. Forty-three percent of the leaks were < 5 mm, 15% were 5 mm, 25% were > 5 mm with 17% not reporting leak size. Additionally, 22% patients with peridevice leak experienced stroke or TIA. Seventy-one (86%) peridevice leaks were managed conservatively. Six patients underwent cardiac surgery, four patients underwent percutaneous closure, one patient was managed with an embolization coil, and one underwent a second Watchman implant.

SURGICAL ABLATION performed at the same time as other cardiac surgery (CPT® codes 33256, 33257, 33258, 33259), and

SURGICAL ABLATION performed without cardiopulmonary bypass when concomitant cardiac surgery is NOT being performed (CPT® codes 33254, 33255, 33265, 33266)

The original atrial maze procedure consisted of a biatrial lesion set derived from a "cut-and-sew" technical approach. Similar lesion sets delivered by cryoenergy or radiofrequency were subsequently developed. Surgical ablation concomitant with cardiac surgery currently takes place in approximately 1 in 5 patients with previous AF, most commonly at the time of a mitral valve procedure but also during aortic and tricuspid procedures or CABG (ACC/Joglar, et al., 2024).

"Although the Cox-Maze procedure is still the golden-standard for AF ablation for many surgeons, it requires the use of cardiopulmonary bypass. As such, the quest for a surgical technique that is as efficacious as the original Cox-Maze procedure, but less invasive, has led to the development of minimally invasive (keyhole) surgical approaches. Hence, a stand-alone minimally invasive, bilateral video assisted thoracoscopic procedure on the beating heart was developed. Although results of such a thoracoscopic approach are good, an important shortcoming of the technique is that the surgeon is in fact blind to the underlying electrophysiological properties of the atria.

In order to overcome their mutual shortcomings and to combine the strengths of a catheter ablation (CA) and a thoracoscopic approach, the hybrid AF approach was developed. Given the incomplete understanding of underlying AF mechanisms and the complexity of persistent forms of AF, the concept of combining the strengths of a minimally invasive epicardial with a percutaneous endocardial approach was originated. With a hybrid procedure, the endocardial approach can be performed single-staged or two-staged, e.g., within six months after the epicardial ablation. It is important to note that the concept of the hybrid procedure requires both an epicardial and an endocardial approach. The strength of a hybrid procedure is highlighted by its complementary nature: the surgeon has direct three-dimensional visualization of the anatomy and can create long-lasting epicardial lesions while the electrophysiologist (EP) uses high-resolution endocardial maps to visualize the underlying substrate" (van der Heijden, et al., 2024).

Surgical Ablation – U.S. Food and Drug Administration (FDA): The Maze procedures are not subject to regulation by the FDA. Any medical devices, drugs, biologics, or tests used as a part of this procedure may be subject to FDA regulation.

Surgical Ablation – Professional Societies/Organizations: The ACC/AHA 2024 Guideline for the Diagnosis and Management of Atrial Fibrillation (ACC/Joglar, et al., 2024) lists the following recommendations regarding surgical ablation:

*(Class of Recommendation [COR] and Level of Evidence [LOE], See Appendix)	**COR***	**LOE***
8.6. Surgical Ablation		
For patients with AF who are undergoing cardiac surgery, concomitant surgical ablation can be beneficial to reduce the risk of recurrent AF.	IIa	B-R
For patients with symptomatic, persistent AF refractory to antiarrhythmic drug therapy, a hybrid epicardial and endocardial ablation might be reasonable to reduce the risk of recurrent atrial arrhythmia.	IIb	B-R
The ACC goes on to note that among patients with AF or AFL, concomitant surgical ablation at the time of cardiac surgery has been shown to reduce the risk of recurrent atrial arrhythmia. However, it is associated with an increased risk of renal dysfunction and pacemaker placement. Among patients with symptomatic, persistent AF, a hybrid procedure combining epicardial and endocardial ablation has been shown to reduce the burden of atrial arrhythmia (ACC/Joglar, et al., 2024).	n/a	n/a

The 2024 AHA/ACC Guideline for the Diagnosis and Treatment of Patients With Hypertrophic Cardiomyopathy (HCM) (Ommen, et al., 2024) includes recommendations on AF

*(Class of Recommendation [COR] and Level of Evidence [LOE], See Appendix)	**COR***	**LOE***
Recommendations on AF 8.4 Management of Patients With HCM and AF		
#6. In patients with HCM and symptomatic AF, as part of a AF rhythm control strategy, catheter ablation for AF can be effective when drug therapy is ineffective, contraindicated, or not the patient's preference	IIa	B-NR
#7. In patients with HCM and AF who require surgical myectomy, concomitant surgical AF ablation procedure can be beneficial for AF rhythm control (Ommen, et al., 2024).	IIa	B-NR

The Society of Thoracic Surgeons (STS) Clinical Practice Guidelines for the Surgical Treatment of Atrial Fibrillation (Wyler von Ballmoos, et al., 2024) lists the following recommendations:

	COR*	**LOE***
Recommendations for mitral valve operations:		

	COR*	LOE*
Surgical ablation for atrial fibrillation is recommended for first-time nonemergent concomitant mitral operations to restore sinus rhythm and improve long-term outcomes.	I	A
Recommendations for operations other than mitral valve surgery:		
Surgical ablation for atrial fibrillation is recommended for any first-time non-emergent concomitant non-mitral operation to restore sinus rhythm and improve long-term outcomes.	I	B-NR
Recommendations regarding stand-alone surgical ablation:		
Surgical ablation for symptomatic atrial fibrillation in the absence of structural heart disease refractory to class I/III antiarrhythmic drugs, catheter-based therapy, or both is reasonable as a primary stand-alone procedure to restore sinus rhythm	IIa	B-NR
Surgical ablation for symptomatic persistent or longstanding persistent atrial fibrillation in the absence of structural heart disease is reasonable as a stand-alone procedure using the Cox-Maze III/IV lesion set as the preferred procedure	IIa	B-NR
Surgical ablation for symptomatic atrial fibrillation in the setting of left atrial enlargement (≥4.5 cm) or more than moderate mitral regurgitation by pulmonary vein isolation alone is not recommended.	III	C
Recommendations for concomitant left atrial appendage management:		
Left atrial appendage obliteration for atrial fibrillation is recommended for all first-time non-emergent cardiac surgery procedures, with or without concomitant surgical ablation, to reduce morbidity from thromboembolic complications.	I	A
Recommendations regarding stand-alone left atrial appendage management:		
Isolated surgical left atrial appendage obliteration may be considered in patients with longstanding persistent atrial fibrillation, a high stroke risk, and contraindications for or failure of long-term oral anticoagulation.	IIb	B-NR
Recommendations for patients being considered for transcatheter valve therapies:		
For patients with symptomatic valve disease and atrial fibrillation, who are deemed of low to intermediate surgical risk, surgical valve repair or replacement with concomitant surgical ablation and left atrial appendage occlusion is reasonable over isolated transcatheter valve repair or replacement alone to restore sinus rhythm and improve long-term outcomes.	IIa	B-NR
Recommendations for all patients with atrial fibrillation		
Multidisciplinary heart team assessment and treatment planning as well as long-term follow-up using periodic continuous electrocardiographic monitoring for rhythm assessment, are recommended to optimize patient outcomes (Wyler von Ballmoos, et al., 2024)	I	C

The STS notes that individuals with symptomatic atrial fibrillation refractory to antiarrhythmic drugs with at least one unsuccessful catheter-based ablation may be referred for stand-alone surgical ablation. An increasing number of stand-alone surgical ablation studies using cryoablation

and a minimally invasive thoracoscopic or robotic-assisted approach have recently shown improved outcomes in safety and effectiveness, with >90% of patients being free from atrial fibrillation at 1 year and >80% at 5 years of follow up. Notably, these results were achieved at established, high-volume centers despite including many patients with long-standing persistent atrial fibrillation. These were not always documented by continuous electrocardiographic monitoring to support the rhythm end points.

Given stronger longitudinal evidence of efficacy and longitudinal freedom from atrial fibrillation, antiarrhythmic drugs, as well as oral anticoagulation after a full biatrial Cox maze, the field awaits more homogeneous or randomized evidence on hybrid or epicardial ablation procedures that adhere to the concept of the Cox maze lesion set. Epicardial ablation with atypical lesions remains exploratory until more robust evidence becomes available (STS/ Wyler von Ballmoos, et al., 2024).

*Classes of Recommendation (COR) and Levels of Evidence (LOE)

Classification of strength of recommendation
Class I (strong; benefit >>> risk): procedure is useful, effective, and beneficial. Recommendation: procedure should be performed.
Class IIA (moderate; benefit >> risk): procedure can be useful, effective, and beneficial. Recommendation: procedure is reasonable.
Class IIB (weak; benefit equal to or greater than risk): effectiveness is unknown, unclear, or uncertain. Recommendation: procedure might be reasonable.
Class III, no benefit (moderate; benefit equals risk): procedure is not useful, effective, or beneficial. Recommendation: procedure should not be performed.
Class III, harm (strong; benefit less than risk): Procedure potentially causes harm or excess mortality and morbidity. Recommendation: procedure should not be performed.

Level of quality of evidence
Level A: high-quality evidence from more than one randomized controlled trial (RCT); meta-analyses or high-quality RCTs; or one or more RCTs corroborated by high-quality registry studies.
Level B randomized: moderate quality evidence from one or more RCTs or meta-analyses of moderate quality.
Level B nonrandomized: moderate quality of evidence from one or more well-designed, well-executed nonrandomized studies, registries, or observational analyses; meta-analyses of such studies.
Level C limited data: randomized or nonrandomized observational or registry studies with limitations of design or execution; meta-analyses of such studies; mechanistic or physiologic investigation in human subjects.
Level C expert opinion: consensus of expert opinion based on clinical experience (Society of Thoracic Surgeons, (Wyler von Ballmoos, et al., 2024/ Badhwar, et al., 2017)

The 2024 European Heart Rhythm Association/Heart Rhythm Society (Tzeis, et al., 2024) recommendations for Surgical and hybrid AF ablation include:

Surgical and hybrid AF ablation	Category of advice	Type of evidence

Surgical and hybrid AF ablation	Category of advice	Type of evidence
Concomitant surgical AF ablation is beneficial in patients with paroxysmal or persistent AF undergoing left atrial open cardiac surgery regardless of prior antiarrhythmic drug failure or intolerance	Advice TO DO	META
Concomitant surgical AF ablation is beneficial in patients with paroxysmal or persistent AF intolerant or refractory to previous antiarrhythmic drug therapy, undergoing closed (non-left atrial open) cardiac surgery	Advice TO DO	META
Biatrial Cox maze procedure or a minimum of PVI plus left atrial posterior wall isolation is beneficial in patients undergoing surgical AF ablation concomitant to left atrial open cardiac surgery	Advice TO DO	RAND
Documentation of exit and/or entrance block across pulmonary veins and completeness of deployed lines is beneficial during surgical AF ablation	Advice TO DO	OPN
Exclusion of the left atrial appendage is beneficial as a part of surgical AF ablation procedures (stand-alone or concomitant)	Advice TO DO	RAND
Concomitant surgical AF ablation is reasonable in patients with paroxysmal or persistent AF prior to initiation of Class I or III antiarrhythmic therapy, undergoing closed (non-left atrial open) cardiac surgery	May be appropriate to do	META
Stand-alone surgical or hybrid ablation is reasonable in symptomatic patients with persistent AF with prior unsuccessful catheter ablation and also in those who are intolerant or refractory to antiarrhythmic drug therapy and prefer a surgical/hybrid approach, after careful consideration of relative safety and efficacy of treatment options	May be appropriate to do	META
Stand-alone surgical or hybrid ablation may be reasonable in symptomatic patients with paroxysmal AF with prior unsuccessful catheter ablations who prefer a surgical/hybrid approach, after careful consideration of relative safety and efficacy of treatment options	Area of uncertainty	RAND

Category of advice

- Advice TO DO = Evidence or general agreement that a given measure is clinically useful and appropriate
- May be appropriate TO DO = Evidence or general agreement that a given measure may be clinically useful and appropriate
- Area of uncertainty = No strong advice can be given, lack of data, inconsistency of data
- Advice NOT to do = Evidence or general agreement that a given measure is not appropriate or harmful

Classification of different types of evidence and respective criteria

- META = Evidence from >1 high-quality RCT; Metaanalyses of high-quality RCTs
- RAND = Evidence from 1 high-quality RCT; Evidence from >1 moderate-quality RCT; Metaanalyses of moderate-quality RCTs
- OBS = Observational studies or registries; Metaanalyses of such studies
- OPN = Randomized, non-randomized, observational or registry studies with limitations of design or execution, case series; Metaanalyses of such studies; Physiological or

mechanistic studies in human subjects; Consensus of expert opinion based on clinical experience (European Heart Rhythm Association/Heart Rhythm Society/Tzeis, et al., 2024)

Surgical Ablation – Literature Review: Concomitant surgical ablation at the time of cardiac surgery has been shown to reduce the risk of recurrent atrial arrhythmia. However, it is associated with an increased risk of renal dysfunction and pacemaker placement (Iribarne, et al., 2019; Huffman, et al., 2017; Huffman, et al., 2016; Gillinov, et al., 2015).

When concomitant cardiac surgery is NOT being performed, comparison between clinical studies is difficult and limited by heterogeneous study populations, use of different lesion sets and energy sources, differences in type of designs and lack of standardized outcome measures and definitions of success. Follow-up time varies across studies as well as definition of procedure success used to assess clinical outcomes. Furthermore, there is no clear consensus among authors regarding patient selection criteria when concomitant cardiac surgery is NOT being performed. Further scientific research, involving well-designed controlled clinical trials with long-term net health outcome data, are still needed to clearly define and establish a role for surgical Maze or modified Maze procedure including endoscopic Maze **–** when concomitant cardiac surgery is NOT being performed **–** whether standalone or as part of a hybrid procedure.

van der Heijden et al. (2023) conducted a randomized controlled trial (HARTCAP-AF trial) that evaluated the effectiveness and safety of hybrid ablation compared to repeat catheter ablation in patients with persistent atrial fibrillation (persAF). Patients, (n=41) > age 18 years with symptomatic (long-standing)-persAF refractory to one or more class I or III antiarrhythmic drugs and no prior (catheter) ablation were included in the study. Patients were randomized to hybrid ablation (n=19) or catheter ablation (n=22). The primary effectiveness outcome measured freedom from any recurrent supraventricular tachyarrhythmia off anti-arrhythmic drugs (AADs), lasting ≥ 5 minutes at 12 months. The secondary effectiveness outcome measured freedom from any recurrent supraventricular tachyarrhythmia off AADs lasting ≥ 30 seconds at 12-month follow-up. Additional outcomes measured the freedom from AAD use, the number of arrhythmia-related re-hospitalizations, and reinterventions such as cardioversions and redo catheter ablations. Changes in quality of life (QOL) were also measured. The primary safety outcome measured major adverse events and complications that occurred within 12 months of follow-up. Secondary safety outcomes measured the total number of serious adverse events. Patients in the HA group received closure of the LAA either using AtriClip (n=17) or the Lariat closure device (n=2). In the CA group, transvenous PVI and the box lesion were created in all patients. Freedom from any recurrent supraventricular tachyarrhythmia off anti-arrhythmic drugs lasting ≥ 30 seconds or ≥ 5 minutes was significantly higher in the HA group compared with the CA group (89% vs 41%, p=0.002; 95% vs 41%, p<0.001, respectively). It was more likely for the HA group compared to the CA group to receive AADs until three months after the procedure but more patients in the HA group were off AADs after 1 year (95% vs 36%, p=0.005). No significant differences were reported between the groups in the number of major adverse events, minor complications, QOL and AF related symptoms. Lastly, median procedure time and length of hospital stay were significantly longer in the HA group, whereas the exposure to radiation dose and time were significantly higher in the CA group. An author noted limitation was that all procedures were conducted in a single, highly specialized center with experienced cardiac surgeons and electrophysiologists, which decreases the generalizability and external validity of the results. Additionally, the authors noted that the study was not double-blinded and the rate of patients in sinus rhythm at one year might be overrated. Limitations also included the small sample size; short-term follow-up and the study was done in the Netherlands and results may not be applicable to other races or ethnic groups. Further studies in large, diverse populations with long-term follow-up are needed to evaluate efficacy, optimize protocols and outcomes.

Doll et al. (2023) conducted a prospective, multi-center, randomized controlled trial (CEASE-AF) that evaluated if hybrid epicardial-endocardial ablation (HA) would have superior effectiveness when compared to catheter ablation (CA), including repeat (rCA), in persistent and longstanding persistent atrial fibrillation (PersAF/LSPAF). Nine hospitals in Poland, Czech Republic, Germany, United Kingdom, and the Netherlands enrolled patients aged 18–75 with symptomatic, drug refractory PersAF and left atrial diameter (LAD) > 4.0 cm or symptomatic LSPAF; and had failed at least one class I or III anti-arrhythmic drugs (AAD). The primary effectiveness outcome measured the freedom from documented AF/atrial flutter (AFL)/atrial tachycardia (AT) episodes >30 s through the 12-months follow-up visits in the absence of Class I or III AADs except for AADs at doses not exceeding previously failed doses. The safety outcome measured the major complications that occurred during the study. Patients (n=154) were randomized (2:1) to either HA (n=102) or CA (n=52). The HA first stage (index procedure) included endoscopic epicardial ablation where pulmonary veins (PV) and left posterior atrial wall were isolated and the left atrial appendage was excluded. Endocardial touch-up ablation was performed 91–180 days post-index procedure. Endocardial CA was performed using current RF catheter technology, PVI was mandatory during the index procedure. Additional ablation strategies were in accordance with current guidelines. Follow-up visits occurred at 3- and 6-months after the first ablation (T0), then 6- and 12-months after T0; to allow for staged endocardial ablation in the HA arm or repeat endocardial ablation in the CA arm. The freedom from documented AF/atrial flutter (AFL)/atrial tachycardia (AT) episodes >30 s through the 12-months was statistically significant in HA when compared to CA (71.6% vs 39.2%, 95% CI 14.3%–48.0%, p<0.001). Major complications through 30-days after index procedures plus 30-days after second stage/rCA were similar between groups, and not statistically significant (HA: 7.8% vs CA: 5.8%, p=0.75). Procedure duration was significantly longer with HA compared to CA (p<0.001). Fluoroscopy time was significantly lower with HA compared to CA (p=0.001). The authors noted the following limitations: all patients in the HA arm had LAA management but the effectiveness LAA exclusion was not evaluated, the different overall number of procedures differs between HA and CA and symptom-driven ECG monitoring was performed at unscheduled visits, which could have underestimated actual failure rates in both arms. Additional limitations included that the study was conducted in specific countries limiting generalizability to other ethnicities, the small sample size and short-term follow-up. Further studies in large, diverse populations with long-term follow-up are needed to evaluate efficacy, optimize protocols and outcomes.

DeLurgio et al. (2022/2020) conducted a multicenter, randomized controlled trial (CONVERGE) that evaluated the effectiveness of the combined hybrid epicardial and endocardial ablation (Hybrid Convergent) for the treatment of persistent and long-standing persistent AF with endocardial catheter ablation. Adults 18–80 years, with symptomatic persistent AF that was refractory or intolerant to at least one class I/III antiarrhythmic drug (AAD) and had a left atrium size of ≤ 6.0 cm. There was no limitation on duration of AF. No health disparities were identified by the investigators. Patients (n=153) were randomized 2:1 to the Hybrid Convergent group (n=101) or the catheter ablation group (n=51). In-person follow-up visits were performed at seven days, one, three, six, and 12 months and included an electrogram and review of medications and adverse events. The trial also included an in-person longer-term follow-up visit at 18 months and phone follow-up at two, three, four, and five years. A total of 96% patients in the Hybrid Convergent group and 98% in the catheter ablation group completed the 12-month visit. Six- and 12-month Holter data were available for 97.1% and 96.1% patients in the Hybrid Convergent group, and 100% and 98% patients in the catheter ablation group. Hybrid Convergent had significant improvement in persistent and long-standing atrial fibrillation (p=0.036) and success off antiarrhythmic drugs (p=0.0128) when compared to catheter ablation. At 18 months using 7-day Holter, 74.0% Hybrid Convergent and 55% CA patients experienced ≥ 90% AF burden reduction, which was clinically significant (p=0.0395) in favor of the Hybrid Convergent group. A total of 2.9% patients had primary safety events within seven days, and 4.9% between eight and 30 days postprocedure. No deaths, cardiac perforations, or atrioesophageal fistulas

occurred. All but one primary safety event resolved. Author noted limitations included: the absence of empirical endocardial posterior wall ablation in the catheter ablation group; only using irrigated radiofrequency catheters for endocardial ablation in both groups; cryoablation was not included and electrical isolation or exclusion of LAA was not performed. Additional limitations included small patient population, unequal randomization and short-term follow-up.

In 2022 DeLurgio et al. evaluated the safety and effectiveness of HC vs CA in the longstanding persistent atrial fibrillation (LSPAF) subgroup from the CONVERGE trial, which is described in detail above. The primary outcome measured freedom from atrial arrhythmias off new or increased dose of previously failed or intolerant antiarrhythmic drugs (AADs) through 12 months. The primary safety outcome measured major adverse events through 30 days with HC. Secondary effectiveness outcomes measured (1) percent of patients achieving ≥ 90% AF burden reduction vs baseline and (2) AF freedom. Sixty-five patients (42.5% of total enrollment) had LSPAF; 38 in HC and 27 in CA. Freedom from AF, AFL, or AT without a new or increased dose of previously failed AAD was significantly higher at 12 and 18 months in the HC arm compared to catheter ablation arm (p=0.022, p=0.006, respectively). Freedom from AF, AFL, or AT off class I or III AADs was significantly higher in the HC arm compared to CA arm at 12 and 18 months 12 months (p=0.031; p=0.038, respectively). In LSPAF patients, the MAE rate in the HA arm was 7.9%, which included 1 cardiac tamponade, 1 stroke, and 1 phrenic nerve injury. No MAEs occurred in the catheter ablation arm. Author noted limitations include the post hoc nature of the analysis and small population size of the subgroups. The authors noted that the data should be interpreted with caution because CIs and P values were not adjusted for multiplicity. Lastly, patients were randomized 2:1 to hybrid convergent and catheter ablation arms, but randomization was not stratified by baseline AF subtype.

MacGregor et al. (2022) retrospectively reported single-center results of 236 patients who underwent stand-alone Cox-Maze IV (CMP-IV) through either a median sternotomy or a right mini-thoracotomy (RMT). A total of 60 patients had paroxysmal AF and 176 had non-paroxysmal AF, of which 91% (161/176) had longstanding persistent AF. Overall freedom from atrial tachyarrhythmias (ATAs) recurrence was 94% (187/199), 95% (124/131), 89% (81/91), 86% (49/57), and 79% (26/33) at 1, 3, 5, 7, and 10 years, respectively. Freedom from ATAs recurrence off AADs was 86% (172/199), 89% (117/131), 76% (69/91), 77%(44/57), and 70%(23/33) at 1, 3, 5, 7, and 10 years, respectively. A limitation of this study is its retrospective design, small sample size and lack of comparator.

Ad et al. (2017) conducted a single-center, prospective observational cohort study including 133 patients. Patients underwent on-pump, minimally invasive through a small right mini-thoracotomy, stand-alone Cox maze III/IV procedure. Of the 133 patients with nonparoxysmal AF, median AF duration was 51 months, 78% had long-standing persistent AF, 22% had persistent AF, and 44% had a previous catheter ablation. A total of 68 patients reached 5 years after surgery. Using the HRS Guidelines definition of sinus rhythm off antiarrhythmic drugs (AAD) with no follow-up catheter ablations, analyses found that success after a single intervention was 88%, 82%, 76%, 74%, and 73%, respectively, at 1, 2, 3, 4, and 5 years after surgery. During the first 5 years of follow-up, there were 13 patients who underwent follow-up catheter ablation procedures (10%) and 15 patients experienced electrical cardioversions (11%). During follow-up, the majority of patients were no longer on anticoagulation at 1 year (78%), 2 years (83%), 3 years (79%), and 4 years (73%) after surgery. All procedures performed with no conversion to midsternotomy, no renal failure, strokes, or operative mortality (<30 days), transient ischemic attack in 1 patient, reoperation for bleeding in 2 patients, and median length of stay was 4 days [3–5.5 days]. A limitation of this study is its small sample size and lack of comparator.

2012 Database report: Based on the Society of Thoracic Surgeons (STS) Database*, the overall operative mortality (30 days) was 0.74% (off- cardiopulmonary bypass [CPB] group, 0.5%; on-

CPB group, 1.7%; P=.7). The rate of any STS complication was 16.43%, with significantly greater rates for the on-CPB group (27.97%vs 13.60%, P<.0001). The overall stroke rate was 0.72%, with a significantly greater incidence for the on-CPB group at 1.26% (P=.017). The renal failure rates were greater for the on-CPB group, with an overall incidence of 2.45% (5.48% vs 1.71%; P=.0001) (STS/Ad, et al., 2012).

> * The STS has maintained a prospective database of patients undergoing cardiothoracic surgery in the United States since 1987. This data is from the STS Adult Cardiac Surgery Database to report on surgical ablation procedures for AF performed as an isolated procedure or concomitantly with other cardiac surgical procedures from 2005 to 2010 (STS/Ad, et al., 2012).

ACTIVE ESOPHAGEAL COOLING DEVICE (HCPCS C1889)

One major risk of cardiac ablation is thermal injury to the esophagus, which is a consequence of the proximity of the posterior wall of the left atrium to the anterior wall of the esophagus. There are several approaches to cooling the esophagus, including open irrigation of cold liquid inside the esophagus and closed-irrigated systems (e.g., expandable esophageal balloon). These methods have been evaluated in different small clinical trials with inconsistent results, and validation of safety and efficacy is still required. Reducing intraluminal esophageal temperature via active cooling has been proposed to minimize the risk of esophageal thermal injury during RF catheter ablation. Vasoconstriction associated with cooling may predispose to ischemia or vascular compromise to the esophagus.

Active esophageal cooling device – U.S. Food and Drug Administration (FDA): The FDA granted a De Novo request for classification of Class II on September 13, 2023, to ensoETM® (Attune Medical). The FDA states the device is "Intended to reduce the likelihood of ablation-related esophageal injury resulting from radiofrequency cardiac ablation procedures and provide gastric decompression and suctioning." FDA identifies this generic type of device as: "Temperature regulation device for esophageal protection during cardiac ablation procedures. This device is placed in the lumen of the esophagus to reduce the likelihood of esophageal injury or a specific adverse event during cardiac ablation procedures. The device uses temperature regulation to control the temperature of the esophagus during cardiac ablation."

The ensoETM device is a silicone tube through which distilled water is pumped in a closed-loop irrigation system: no water enters the gastrointestinal tract of the patient. There is an additional inner lumen that can be used for gastric aspiration like a standard nasogastric tube. The non-patient end of the device is connected to a mobile console that pumps the water and controls its temperature. The ensoETM device maintains the water at a thermostat-controlled set temperature chosen by the operator between 4 degrees Celsius and 42 degrees Celsius.

Active esophageal cooling device – Professional Societies/Organizations: The ACC/AHA 2024 Guideline for the Diagnosis and Management of Atrial Fibrillation (ACC/Joglar, et al., 2024) does not address esophageal cooling.

The 2024 European Heart Rhythm Association/Heart Rhythm Society (Tzeis, et al., 2024) recommendations for esophageal temperature management include:

7. Procedural management and techniques esophageal temperature management	Category of advice	Type of evidence
Use of an esophageal temperature probe may be reasonable during thermal AF ablation procedures to monitor esophageal temperature and help guide energy delivery.	Area of uncertainty	RAND

Category of advice

- Advice TO DO = Evidence or general agreement that a given measure is clinically useful and appropriate
- May be appropriate TO DO = Evidence or general agreement that a given measure may be clinically useful and appropriate
- Area of uncertainty = No strong advice can be given, lack of data, inconsistency of data
- Advice NOT to do = Evidence or general agreement that a given measure is not appropriate or harmful

Classification of different types of evidence and respective criteria

- META = Evidence from >1 high-quality RCT; Metaanalyses of high-quality RCTs
- RAND = Evidence from 1 high-quality RCT; Evidence from >1 moderate-quality RCT; Metaanalyses of moderate-quality RCTs
- OBS = Observational studies or registries; Metaanalyses of such studies
- OPN = Randomized, non-randomized, observational or registry studies with limitations of design or execution, case series; Metaanalyses of such studies; Physiological or mechanistic studies in human subjects; Consensus of expert opinion based on clinical experience (European Heart Rhythm Association/Heart Rhythm Society/Tzeis, et al., 2024)

Active esophageal cooling device – Literature Review: Sanchez et al. (2023) analyzed retrospective data from 30 hospitals to determine the atrioesophageal fistula (AEF) rate with use of the ensoETM esophageal cooling device. Patients undergoing RF catheter ablation for the treatment of AF were included. The number of patients treated with active esophageal cooling at each hospital system ranged from 212 to 1700. In total, 14,224 individuals used the ensoETM esophageal cooling device.

- The authors reported they looked at a cohort of patients treated across the 25 systems before the adoption of active esophageal cooling device and found a total of 16 AEFs occurred, yielding an AEF rate of 0.146%. In the cohort of patients treated after adoption of active esophageal cooling device, no AEFs were identified, representing an AEF rate of 0% ($P < 0.0001$).
- The authors noted the following study limitations:
  - Study design included retrospectively gathered data
  - Data collection at each site was not standardized
  - Different methods of determining event rates at different hospitals

Leung et al. (2021) conducted a single-center, randomized trial ('IMPACT' study) to investigate the ability of the ensoETM® device to protect the esophagus from thermal injury. A total of 188 participants were recruited of whom 120 (60 protected and 60 control) underwent catheter ablation. Endoscopic examination was performed at 7 days post-ablation and esophageal injury was scored.

- The protected group received the ensoETM probe. After using transesophageal echocardiography to guide transseptal puncture, the probe was withdrawn and an ensoETM probe was introduced in its place, connected to a mobile console. The position was confirmed radiographically, aiming to place the distal end of the device below the diaphragm. Before beginning ablation on the posterior part of the left atrium, the probe

was set to cooling mode at 4 degrees Celsius for at least 10 min. Cooling continued until ablation was complete.

- The control group received no cooling method. A single-sensor temperature probe was placed in the esophagus by the attending anesthetist and adjusted approximately to the site of ablation. Adjustment of the position of the probe during ablation was performed by the anesthetist under the direction of the operating electrophysiologist with the objective of keeping the tip of the probe as close as possible to the site of ablation whenever the site was within 1 cm of the esophagus. RF delivery was suspended if the temperature indicated by the probe exceeded 38 degrees Celsius and RF was not resumed at that location until the temperature fell below 37 degrees Celsius. To avoid delay, operators often moved to a location distant from the esophagus to continue work while waiting for the temperature to fall.
- Thermal injury to the mucosa was significantly more common in the control group than in those receiving esophageal protection (12/60 vs. 2/60; P = 0.008), with a trend toward reduction in gastroparesis (6/60 vs. 2/60, P = 0.27). There was no difference between groups in the duration of RF or in the force applied (P value range = 0.2–0.9). Procedure duration and fluoroscopy duration were similar (P = 0.97, P = 0.91, respectively).
- Authors note these limitations:
  - A larger trial would be required to answer the question whether the use of the ensoETM device eliminates the possibility of atrio-esophageal fistula formation
  - Operators participating in the study were not and could not have been blinded to the randomization.
  - A single sensor probe was used in the control group. Results found in the control group may not be generalizable to temperature measurement using other measurement devices.

At this time, there is insufficient evidence in the peer-reviewed published literature in the form of large, well-designed randomized trials reported for the routine use of the ensoETM® esophageal cooling device to reduce ablation-related esophageal injury resulting from radiofrequency cardiac ablation procedures and therefore this remains EIU at this time.

The IMPACT II trial (NCT04577859) is currently recruiting.

Medicare Coverage Determinations

	Contractor	Determination Name/Number	Revision Effective Date
NCD	National	Percutaneous Left Atrial Appendage Closure (LAAC) (20.34)	2/8/2016
LCD		No Determination found	

Note: Please review the current Medicare Policy for the most up-to-date information.
(NCD = National Coverage Determination; LCD = Local Coverage Determination)

Appendix

The American College of Cardiology/ American Heart Association (ACC/AHA) 2024 Guideline for the Diagnosis and Management of Atrial Fibrillation (ACC/Joglar, et al., 2024)

Applying American College of Cardiology/American Heart Association Class of Recommendation and Level of Evidence to Clinical Strategies, Interventions, Treatments, or Diagnostic Testing in Patient Care* (Updated May 2019)

The Class (Strength) of Recommendation (COR) indicates the strength of recommendation, encompassing the estimated magnitude and certainty of benefit in proportion to risk.

Class I – Strong (is recommended)
Class 2a – Moderate (is reasonable)
Class 2b – Weak (may/might be reasonable)
Class 3 – No benefit (Moderate) (is not recommended)
Class 3 – Harm (Strong) (potentially harmful)

The Level (Quality) of Evidence (LOE) rates the quality of scientific evidence supporting the intervention on the basis of the type, quantity, and consistency of data from clinical trials and other sources.

Level A – High quality evidence from more than one randomized clinical trial, Meta-analyses of high-quality randomized clinical trials, One or more randomized clinical trials corroborated by high-quality registry.
Level B-R – Randomized. Moderate quality evidence from one or more randomized clinical trials, Meta-analyses of moderate-quality randomized clinical trials.
Level B-NR – Non-randomized. Moderate quality evidence from one or more well-designed, well-executed nonrandomized studies, observational studies, or registry studies, Meta-analyses of such studies.
Level C-LD – Limited data. Randomized or nonrandomized observational or registry studies with limitations of design or execution, Meta-analyses of such studies, Physiological or mechanistic studies of human subjects.
Level C-EO – Expert Opinion. Consensus expert opinion based on the clinical experience

*The outcome or result of the intervention should be specified (an improved clinical outcome or increased diagnostic accuracy or incremental prognostic information).

Coding Information

Notes:

1. This list of codes may not be all-inclusive since the American Medical Association (AMA) and Centers for Medicare & Medicaid Services (CMS) code updates may occur more frequently than policy updates.
2. Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement.

Catheter Ablation

Considered Medically Necessary when criteria in the applicable policy statements listed above are met and when used to report cardiac catheter ablation with pulmonary vein isolation:

CPT®* Codes	Description
93656†	Comprehensive electrophysiologic evaluation including transseptal catheterizations, insertion and repositioning of multiple electrode catheters with intracardiac catheter ablation of atrial fibrillation by pulmonary vein isolation, including intracardiac electrophysiologic 3-dimensional mapping, intracardiac echocardiography including imaging supervision and interpretation, induction or attempted induction of an

CPT®* Codes	Description
	arrhythmia including left or right atrial pacing/recording, right ventricular pacing/recording, and His bundle recording, when performed
93657†	Additional linear or focal intracardiac catheter ablation of the left or right atrium for treatment of atrial fibrillation remaining after completion of pulmonary vein isolation (List separately in addition to code for primary procedure)

†**Note: Considered Medically Necessary when used to report repeat cardiac catheter ablation for an individual with recurrent symptomatic atrial fibrillation.**

Considered Not Medically Necessary when used to report Vein of Marshall alcohol ablation (VOM ethanol infusion):

CPT®* Codes	Description
93799	Unlisted cardiovascular service or procedure

Considered Experimental/Investigational/Unproven when used to report use of an active esophageal cooling device during cardiac catheter ablation:

HCPCS Codes	Description
C1889	Implantable/insertable device, not otherwise classified

Percutaneous Approaches to Occlude the Left Atrial Appendage (LAA)

Considered Medically Necessary when criteria in the applicable policy statements listed above are met and when used to report percutaneous transcatheter closure of the left atrial appendage for non-valvular atrial fibrillation for the prevention of stroke:

CPT®* Codes	Description
33340	Percutaneous transcatheter closure of the left atrial appendage with endocardial implant, including fluoroscopy, transseptal puncture, catheter placement(s), left atrial angiography, left atrial appendage angiography, when performed, and radiological supervision and interpretation

Cardiac Surgery-LAA Exclusion/Excision

Considered Medically Necessary when criteria in the applicable policy statements listed above are met and when used to report surgical closure of the left atrial appendage (e.g., excision, isolation via stapling, oversewing, ligation, plication, clip) for the prevention of stroke in conjunction with other cardiac surgical procedures:

CPT®* Codes	Description
33268	Exclusion of left atrial appendage, open, performed at the time of other sternotomy or thoracotomy procedure(s), any method (eg, excision, isolation via stapling, oversewing, ligation, plication, clip) (List separately in addition to code for primary procedure)

Considered Not Medically Necessary when used to report closure of the left atrial appendage NOT performed in conjunction with an open cardiac surgical procedure:

CPT®* Codes	Description
33267	Exclusion of left atrial appendage, open, any method (eg, excision, isolation via stapling, oversewing, ligation, plication, clip)
33269	Exclusion of left atrial appendage, thoracoscopic, any method (eg, excision, isolation via stapling, oversewing, ligation, plication, clip)

Considered Experimental/Investigational/Unproven when used to report closure of a peridevice leak (PDL) after a left atrial appendage occlusion:

CPT®* Codes	Description
33999	Unlisted procedure, cardiac surgery

Surgical Ablation

Considered Medically Necessary when used to report the surgical Maze or modified Maze procedure in an individual with atrial fibrillation who is undergoing cardiac surgery:

CPT®* Codes	Description
33256	Operative tissue ablation and reconstruction of atria, extensive (eg, maze procedure); with cardiopulmonary bypass
33257	Operative tissue ablation and reconstruction of atria, performed at the time of other cardiac procedure(s), limited (eg, modified maze procedure) (List separately in addition to code for primary procedure)
33258	Operative tissue ablation and reconstruction of atria, performed at the time of other cardiac procedure(s), extensive (eg, maze procedure), without cardiopulmonary bypass (List separately in addition to code for primary procedure)
33259	Operative tissue ablation and reconstruction of atria, performed at the time of other cardiac procedure(s), extensive (eg, maze procedure), with cardiopulmonary bypass (List separately in addition to code for primary procedure)

Considered Experimental/Investigational/Unproven when used to report Surgical Maze or modified Maze procedure including endoscopic Maze as a part of a hybrid convergent procedure when concomitant cardiac surgery is not performed:

CPT®* Codes	Description
33254	Operative tissue ablation and reconstruction of atria, limited (eg, modified maze procedure)

CPT®* Codes	Description
33255	Operative tissue ablation and reconstruction of atria, extensive (eg, maze procedure); without cardiopulmonary bypass
33265	Endoscopy, surgical; operative tissue ablation and reconstruction of atria, limited (eg, modified maze procedure), without cardiopulmonary bypass
33266	Endoscopy, surgical; operative tissue ablation and reconstruction of atria, extensive (eg, maze procedure), without cardiopulmonary bypass

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Revision Details

Type of Revision	Summary of Changes	Date

Annual review	• Revised policy statements for surgical ablation (surgical Maze or modified Maze procedure)	10/15/2024
Annual Review	• Title change from Nonpharmacological Treatments for Atrial Fibrillation • Added policy statement for repeat cardiac catheter ablation • Added policy statement for active esophageal cooling device • Revised policy statements for: ➢ Cardiac catheter ablation ➢ Percutaneous transcatheter closure of the left atrial appendage (LAA) ➢ Surgical ablation (surgical Maze or modified Maze procedure)	3/15/2024
Annual Review	• Added policy statement for transcatheter ablation for atrial fibrillation and heart failure. • Removed policy statement criteria for surgical closure of the left appendage	12/15/2023