Clinical UM Guideline

Subject:	Transcatheter Ablation of Arrhythmogenic Foci in the Pulmonary Veins as a Treatment of Atrial Fibrillation or Atrial Flutter (Radiofrequency and Cryoablation)		
Guideline #:	CG-MED-64	**Publish Date:**	10/01/2019
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Description

This document addresses transcatheter radiofrequency ablation and cryoablation of arrhythmogenic foci in the pulmonary veins for the treatment of atrial fibrillation or atrial flutter.

Note: Please see the following related documents for additional information:
- CG-SURG-05 Maze Procedure
- CG-SURG-55 Intracardiac Electrophysiological Studies (EPS) and Catheter Ablation

Clinical Indications

Medically Necessary:

Transcatheter radiofrequency ablation or cryoablation of arrhythmogenic foci in the pulmonary veins is considered **medically necessary** as a treatment of individuals with symptomatic (paroxysmal or persistent) atrial fibrillation.

Not Medically Necessary:

Transcatheter radiofrequency ablation or cryoablation of arrhythmogenic foci in the pulmonary veins is considered **not medically necessary** when the medically necessary criteria are not met and for all other indications, including but not limited to treatment of asymptomatic atrial fibrillation.

Transcatheter radiofrequency ablation or cryoablation of arrhythmogenic foci in the pulmonary veins is considered **not medically necessary** for treatment of atrial flutter.

Coding

The following codes for treatments and procedures applicable to this guideline are included below for informational purposes. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement policy. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

CPT	
93656	Comprehensive electrophysiologic evaluation including transseptal catheterizations, insertion and repositioning of multiple electrode catheters with induction or attempted induction of an arrhythmia including left or right atrial pacing/recording when necessary, right ventricular pacing/recording when necessary, and His bundle recording when necessary with intracardiac catheter ablation of atrial fibrillation by pulmonary vein isolation
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
ICD-10 Procedure	
025S3ZZ	Destruction of right pulmonary vein, percutaneous approach
025T3ZZ	Destruction of left pulmonary vein, percutaneous approach
ICD-10 Diagnosis	
I48.0	Paroxysmal atrial fibrillation
I48.11-I48.19	Persistent atrial fibrillation
I48.20-I48.21	Chronic atrial fibrillation
I48.91	Unspecified atrial fibrillation

Discussion/General Information

Atrial fibrillation (AF) is the most common type of heart arrhythmia. According to the Centers for Disease Control and Prevention an estimated 2.7-6.1 million people in the United States have AF. The prevalence of AF in Americans younger than 65 years of age is 2%, while approximately 9% of adults 65 years and older (CDC, 2017) have AF. The underlying mechanism of AF involves interplay between electrical triggering events and the myocardial substrate that permits propagation and maintenance of the aberrant electrical circuit. The most common focal trigger of AF appears to be located within the cardiac muscle that extends into the pulmonary veins.

Atrial fibrillation accounts for approximately one-third of the hospitalizations for cardiac rhythm disturbances. Symptoms of AF (for example, palpitations or dyspnea) are primarily related to poorly controlled or irregular heart rate. The loss of AV synchrony results in a decreased cardiac output, which can be significant in individuals with compromised cardiac function. In addition, individuals with AF are at higher risk for stroke, and anticoagulation is typically recommended. AF is also associated with other conditions, such as heart failure, valvular heart disease, hypertension and diabetes. Although episodes of AF can be converted to normal sinus rhythm using either pharmacologic or electroshock conversions, the natural history of AF is one of recurrence. This is thought to be related to fibrillation-induced anatomic and electrical remodeling of the atria.

Atrial fibrillation can be subdivided into paroxysmal (self-terminating), persistent (non-self-terminating), or permanent. Treatment strategies can be broadly subdivided into rate control (the ventricular rate is controlled and the atria are allowed to fibrillate) or rhythm control (there is an attempt to reestablish and maintain normal sinus rhythm). Rhythm control has long been considered an important treatment goal for AF management, although this has been recently challenged by the results of two randomized trials, both of which reported that pharmacologically maintained rhythm control offers no improvement in mortality compared to rate control. This finding cannot necessarily be extrapolated to rhythm control using ablative techniques however, since antiarrhythmic drug therapy may be associated with increased mortality. For individuals with persistent AF, rhythm control typically involves initial pharmacologic or electronic cardioversion, followed by pharmacologic maintenance of normal sinus rhythm. However, episodes of recurrent AF are typical and individuals may require multiple episodes of cardioversion. Implantable defibrillators, which are designed to detect and terminate an episode of AF, may be an alternative for individuals who would otherwise require serial cardioversions. Individuals with paroxysmal AF, by definition, do not require cardioversion but may be treated pharmacologically to prevent further episodes of AF. Treatment of permanent AF focuses on rate control, using either pharmacologic therapy or ablation of the AV node, followed by ventricular pacing. Although AV nodal ablation produces symptomatic improvement, it does require lifelong anticoagulation (due to the ongoing fibrillation of the atria), loss of AV synchrony and lifelong pacemaker dependency. Implantable atrial defibrillators are contraindicated for individuals with permanent AF.

The above treatment options are not considered curative. A variety of ablative procedures have been researched in an attempt to modify the arrhythmia so that drug therapy becomes more effective or to potentially cure the condition. Ablative approaches focus on interruption of the electrical pathways that contribute to atrial fibrillation. The Maze procedure, an open surgical procedure often combined with other cardiac surgeries, is an ablative procedure involving sequential atriotomy incisions designed to create electrical barriers that prevent the maintenance of AF. Since the inception of this technique in the early 1990's, there has been a progressive understanding of the underlying electrical pathways in the heart, such that catheter-based radiofrequency procedures have become feasible. Radiofrequency ablation is a widely used technique for a variety of supraventricular arrhythmias, when intracardiac mapping identifies a discrete arrhythmogenic focus that can be the target of ablation. The situation is more complex for AF, since there is not a single arrhythmogenic focus. However, the recent recognition that the triggering foci are commonly located within the myocytes extending into the pulmonary veins creates a potential target for ablation. Three basic strategies have emerged: focal ablation within the pulmonary veins, as identified by electrophysiologic mapping; segmental ostial ablation guided by pulmonary vein potential (electrical approach); or circumferential pulmonary vein ablation (anatomic approach). Circumferential pulmonary vein ablation appears to be the preferred approach at this time.

In 2017, the Heart Rhythm Society (HRS), in conjunction with other organizations, published a consensus statement addressing use of catheter and surgical ablation of atrial fibrillation (Calkins, 2017). The consensus statement notes the following for catheter ablation of AF:

> As demonstrated in a large number of published studies, the primary clinical benefit from catheter ablation of AF is an improvement in quality of life (QOL) resulting from elimination of

> arrhythmia-related symptoms such as palpitations, fatigue, or effort intolerance. Thus, the primary selection criterion for catheter ablation should be the presence of symptomatic AF.

In 2015, the Agency for Healthcare Research and Quality (AHRQ) issued an evidence-based review for catheter ablation for treatment of atrial fibrillation which concludes:

> Catheter ablation for the treatment of AF is increasingly being performed on symptomatic patients as an alternative to medical management, or when medical management has been ineffective or not tolerated. AF ablation is typically recommended only for symptomatic patients; asymptomatic patients are usually managed with anticoagulation and/or rate control as needed. The outcomes of this procedure may depend on patient characteristics such as age, AF type, and presence of structural heart disease, as well as on experience of the operator and methods and technologies used during the procedure. Relief of symptoms is a primary reason for considering catheter ablation as a treatment strategy.

The published literature on radiofrequency pulmonary vein ablation reflects its evolving nature, dominated by reports of the technical capability of different mapping and ablation strategies. For example, catheters with different arrays of electrodes have been specifically developed for pulmonary vein ablation and various authors have described different ablation parameters. Published studies consist mostly of single institution case series; some studies included only subjects with paroxysmal AF, while others included both paroxysmal and persistent AF. In general, the success rate appears greater for paroxysmal AF.

While multi-center randomized trials comparing radiofrequency PVA to ongoing drug therapy are currently lacking and the optimal ablation technique, including the regions of the pulmonary veins and left atrium to be ablated, continues to be refined, the numbers of individuals treated by catheter ablation worldwide and reported to surveyors (Cappato, 2005) are large with an increasing percentage undergoing transcatheter radiofrequency PVA in preference to other techniques (6600 of 10,199 in 2002). While the survey recognizes the variation in mapping and procedural techniques utilized, an average of 52% of subjects were cured of their AF with antiarrhythmic drugs no longer being required, with an additional 23.9% cured using formerly ineffective antiarrhythmic drug therapy. PVA contributed to about two-thirds of these outcome figures.

A 2004 literature review by Finta and Haines, analyzed 19 trials including 2148 participants undergoing focal ablation and pulmonary vein isolation or linear ablation (compartmentalization) of the right atrium with or without left atrium. Of these participants, 1991 underwent either focal ablation or isolation of pulmonary veins. Although the majority had paroxysmal atrial fibrillation (AF), participants with persistent AF who had failed previous antiarrhythmic drug therapy were also included. For the participants treated with a pulmonary vein ablation procedure, the review revealed approximately 70% had no recurrence of their AF at a median follow-up of 12.6 months, without the use of antiarrhythmic drugs.

Pappone and colleagues (2003), in a non-randomized study of 1171 participants with symptomatic AF, compared outcomes of PVA using radiofrequency energy in 589 subjects with antiarrhythmic therapy in 582 subjects with a median follow-up of 900 days. Survival, AF recurrence and quality of life all significantly favored the PVA treated group. Several other studies have also reported improved quality of life measures following successful PVA in individuals with symptomatic AF.

Another energy source being studied for transcatheter treatment of individuals with AF is cryoablation. It is hoped to be as effective as radiofrequency and ultimately safer, potentially reducing the incidence of complications. De Ponti (2005) reports:

> Cryothermal energy ablation causes less or minimal endothelial disruption, maintenance of extracellular collagen matrix and no collagen contracture related to thermal effects. Moreover, lower incidence of thrombus formation is reported with cryoenergy as compared to radiofrequency energy ablation. For these characteristics, cryothermal energy ablation can be considered an ideal and safer energy source also for pulmonary vein ablation and the incidence of both pulmonary veins stenosis and thromboembolic events is expected to be dramatically reduced by using cryoablation. On the other hand, the presence of high blood flow in the pulmonary vein may represent a considerable heat load, which may limit the size and depth of the lesion produced by cryothermal energy at the os of the pulmonary vein. Moreover, the longer time required to produce a permanent lesion may relevantly reflect on procedure duration, limiting the clinical use of this theoretically optimal energy source… Importantly, the early cryoablation experience has not evidenced, so far, development of pulmonary veins stenosis following ablation. Technologic evolution is now aimed to develop new catheter designs for circumferential ostial ablation of the pulmonary veins, with the option of deploying in the pulmonary veins an inflatable balloon to reduce the heat load related to blood flow. These devices are to be tested in a large patient cohort to assess whether these technological improvements will lead to optimization of the use of cryothermal energy, maximizing the advantages of this new technology and limiting the drawbacks encountered in its clinical use.

The STOP-AF trial (Packer, 2013) assessed the safety and effectiveness of a cryoballoon ablation technology. Participants with documented symptomatic paroxysmal AF and previously failed therapy with greater than or equal to one membrane active antiarrhythmic drug underwent 2:1 randomization to either cryoballoon ablation (n=163) or drug therapy (n=82). A 90-day blanking period allowed for optimization of antiarrhythmic drug therapy and re-ablation if necessary. Effectiveness of the cryoablation procedure versus drug therapy was determined at 12 months. Participants had highly symptomatic AF (78% paroxysmal, 22% early persistent) and experienced failure of at least one antiarrhythmic drug. Cryoablation produced acute isolation of three or more PVs in 98.2% and all four PVs in 97.6% of participants. PV isolation was achieved with the balloon catheter alone in 83%. At 12 months, treatment success was 69.9% (114 of 163) of cryoablation participants compared with 7.3% of antiarrhythmic drug participants (absolute difference, 62.6% [p<0.001]). Sixty-five (79%) drug-treated participants crossed over to cryoablation during 12 months of study follow-up due to recurrent, symptomatic AF, constituting drug treatment failure. There were 7 of the resulting 228 cryoablated participants (3.1%) with a greater than 75% reduction in PV

area during 12 months of follow-up. Twenty-nine of 259 procedures (11.2%) were associated with phrenic nerve palsy as determined by radiographic screening; 25 of these had resolved by 12 months. Cryoablation participants had significantly improved symptoms at 12 months. A limitation of the study is the lack of a radiofrequency (RF) ablation arm.

In a single center observational study, Vogt and colleagues (2013), reported follow-up results for 605 participants who underwent cryoablation for symptomatic, paroxysmal or persistent AF. Follow-up results were reported in 451 participants beyond 12 months (mean 30 months), 61% (n=278) of whom were free of AF recurrence with no need for repeat procedures after a 3-month blanking period. After 1, 2 and 3 repeat procedures, rates of freedom from AF were 74.9%, 76.2%, and 76.9%, respectively. The most common acute adverse event reported included phrenic nerve palsy (PNP), occurring in 12 participants (2%), all of which resolved within 3 to 9 months. The study reported one case of pericardial tamponade, one pericardial effusion, and two strokes.

The second generation version cryoballoon devices for pulmonary vein isolation in treatment of paroxysmal atrial fibrillation have been developed with modifications designed to improve procedural outcomes with respect to the first generation device. A case series by Chierchia and colleagues (2014) reported 1-year follow up on 42 participants who underwent PVI with 28 mm cryoballoon advance (CB-A) (Artic Front Advance, Medtronic Inc., Minneapolis, MN) for paroxysmal AF, with 100% of the PVs isolated with the cryoballoon. After a single procedure, 78% of participants reported freedom of AF off-antiarrhythmic drug treatment at 1 year follow-up (mean 11.6 11.6 ± 2.0 months). Including blanking period of 3 months, participant success rate was reported at 83%. The most common acute adverse event was PNP, occurring in 19% of the population, of which PNP reverted during follow-up period. Metzner and colleagues report results from 50 participants with paroxysmal (n=36) or short-standing persistent AF (n=14) who underwent cryoballoon-based pulmonary vein isolation. Participants were assessed in an outpatient clinic at 3, 6 and 12 months including Holter echocardiograms and telephonic interviews. Recurrence was defined as a symptomatic or documented arrhythmic episode of greater than 30 seconds excluding 3-month blanking period. Follow-up results were reported in 49 of 50 participants (98%) with a mean follow-up duration of 440 ± 39 days. A total of 39 (80%) participants remained in sinus rhythm. Of the remaining 10 participants, 8 required a second procedure using RF ablation. One out of 50 participants (2%) developed PNP.

In 2016, Kuck and colleagues reported results from a randomized controlled trial comparing cryoablation (n=378) to RFA (n=384) in individuals with symptomatic drug-refractory paroxysmal AF (FIRE AND ICE trial). The authors concluded that:

> The primary efficacy end point occurred in 138 patients in the cryoballoon group and in 143 in the radiofrequency group (1-year Kaplan–Meier event rate estimates, 34.6% and 35.9%, respectively; hazard ratio, 0.96; 95% confidence interval [CI], 0.76 to 1.22; P<0.001 for noninferiority). The primary safety end point occurred in 40 patients in the cryoballoon group and in 51 patients in the radiofrequency group (1-year Kaplan–Meier event rate estimates, 10.2% and 12.8%, respectively; hazard ratio, 0.78; 95% CI, 0.52 to 1.18; P=0.24).

> In this randomized trial, cryoballoon ablation was noninferior to radiofrequency ablation with respect to efficacy for the treatment of patients with drug-refractory paroxysmal atrial fibrillation, and there was no significant difference between the two methods with regard to overall safety.

Although most reports involve the use of PVA in individuals with AF who remain symptomatic despite drug therapy, a small pilot study by Wazni and colleagues in JAMA (2005), reported a randomized trial comparing pulmonary vein isolation using radiofrequency ablation to antiarrhythmic drugs as first-line treatment of symptomatic AF. Although AF recurrence (the primary study endpoint) was lower in the PVA group in the 1-year follow-up period, the authors acknowledge the sample size (70 subjects) and 1-year follow-up period were not adequate to assess therapeutic effects on certain important outcomes such as stroke. Also, larger studies are needed to confirm the safety and efficacy of pulmonary vein isolation for this purpose, and until these are performed, this should not be considered standard of care as first-line therapy for AF.

However, according to the 2014 AHA/ACC/HRS guideline for the management of patients with atrial fibrillation, the Society includes recommendations for the treatment of symptomatic paroxysmal AF based on results from two more recent randomized controlled trials which compared RFA as first-line therapy with antiarrhythmic drug therapy for rhythm control. In the summary authors reported:

> The RAAFT (Randomized Ablation Versus Antiarrhythmic Drugs for Atrial Fibrillation Treatment)-2 trial compared the efficacy of AF catheter ablation with that of antiarrhythmic drug therapy as first-line therapy for rhythm control in 127 patients (88% with paroxysmal AF) with a higher 1-year freedom from AF (45% versus 28%; P=0.02). The MANTRA-PAF (Medical Antiarrhythmic Treatment or Radiofrequency Ablation in Paroxysmal Atrial Fibrillation) trial compared AF catheter ablation with antiarrhythmic drug therapy as first-line therapy in 294 patients. At the 24-month follow-up, more patients in the ablation group were free from any AF or symptomatic AF, and quality of life was significantly better. However, total AF burden was not significantly different between the 2 groups, and major complications requiring intervention were more common in the ablation group. On the basis of these data, radiofrequency catheter ablation may be considered as first-line therapy in select patients before a trial of antiarrhythmic drug therapy when a rhythm-control strategy is desired.

Another study, the Catheter Ablation vs Anti-arrhythmic Drug Therapy for Atrial Fibrillation (CABANA) trial (NCT00911508) is the largest randomized, open label trial of ablation with overall goal of establishing the appropriate roles for medical and ablative intervention for AF. The study enrolled 2,204 participants at 126 sites worldwide from 2009 to 2016. Packer and colleagues (2019) presented the primary results from the CABANA trial on cardiovascular outcomes and mortality. The trial did not meet its primary end point in the intention-to-treat analysis. Mark and colleagues (2019) reported results for the prespecified secondary end point, with increased quality of life (QOL) at 12 months using several scales validated in individuals with AF.

The AHA defines atrial flutter as an arrhythmia that spreads through the atria at a regular, very rapid rate causing the upper chambers of the heart to contract quickly. Typical atrial flutter is a less common arrhythmia than AF in

clinical practice, although has similar symptoms and complications. Atrial flutter can be found concurrently in individuals with AF. According to January and colleagues (2014) atrial flutter may arise during treatment with an antiarrhythmic administered for treatment of recurrent AF. "Catheter ablation of the cavotricuspid isthmus is effective for prevention of recurrent atrial flutter in these patients while allowing continued antiarrhythmic treatment to prevent recurrent AF."

The 2019 American Heart Association/American College of Cardiology/Heart Rhythm Society (AHA/ACC/HRS) focused update of the 2014 guideline for the management of atrial fibrillation, provides recommendations for AF catheter ablation in the restoration of sinus rhythm not as a sole intent of obviating the need for anticoagulation. The authors further concluded that cryoballoon ablation can be used as an alternative to point-by-point RF ablation to achieve PVI. The guideline does not address use of radiofrequency ablation or cryoablation for PVI in the treatment of atrial flutter.

Definitions

Arrhythmogenic: Producing or promoting arrhythmia.

Atrial fibrillation: A supraventricular (originating in the atria) tachyarrhythmia characterized by uncoordinated atrial activation and ineffective atrial contraction. Characteristics on an ECG include 1) irregular R-R intervals (when atrioventricular [AV] conduction is present), 2) absence of distinct repeating P waves, and 3) irregular atrial activity.

The classifications of AF are defined by the AHA/ACC/HRS Guidelines for the management of AF as follows (January, 2014):

- Paroxysmal AF - AF that terminates spontaneously or with intervention within 7 days of onset. Episodes may recur with variable frequency.
- Persistent AF - Continuous AF that is sustained greater than 7 days.

Atrial flutter: A condition less common than AF, the heart's electrical signals spread through the atria in a fast and regular rhythm.

Foci: Plural of focus, the origin or center of a disseminated disease.

Myocardial substrate: Myocardial cells that is capable of receiving and responding to electrical impulses.

Symptomatic atrial fibrillation: Atrial fibrillation with one or more of the following symptoms, including but not limited to: palpitations, chest pain, dyspnea, dizziness, fatigue, hypotension, syncope or heart failure. (Nabauer, 2009; AHA/ACA/HRS, 2014)

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The use of specific product names is illustrative only. It is not intended to be a recommendation of one product over another, and is not intended to represent a complete listing of all products available.

History

Status	Date	Action
	10/01/2019	Updated Coding section with 10/01/2019 ICD-10-CM changes; added I48.11-I48.19, I48.20-I48.21 replacing I48.1, I48.2.
Reviewed	06/06/2019	Medical Policy & Technology Assessment Committee (MPTAC) review. Updated Discussion, References and Websites sections.
Reviewed	09/13/2018	MPTAC review. Updated Discussion, References and Websites sections.
New	11/02/2017	MPTAC review. Initial document development. Moved content from MED.00064 Transcatheter Ablation of Arrhythmogenic Foci in the Pulmonary Veins as a Treatment of Atrial Fibrillation or Atrial Flutter (Radiofrequency and Cryoablation) to new clinical utilization management guideline document with the same title.