Anthem

Clinical UM Guideline

Subject: Transcatheter Ablation of Arrhythmogenic Foci in the Pulmonary Veins
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Description

This document addresses transcatheter ablation 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 Cardiac Electrophysiological Studies (EPS) and Catheter Ablation
- SURG.00126 Irreversible Electroporation

Clinical Indications

Medically Necessary:

Transcatheter ablation of arrhythmogenic foci in the pulmonary veins is considered **medically necessary** as a treatment of *symptomatic* individuals with **one** of the following:

1. Recurrent (2 or more episodes) ***paroxysmal*** (terminates spontaneously or with intervention within 7 days of onset) atrial fibrillation *as an alternative* to medical therapy; **or**
2. ***Persistent*** (sustained greater than 7 days) atrial fibrillation when refractory or intolerant to **one or more** antiarrhythmic drugs (or has a contraindication to all appropriate antiarrhythmic drug therapy).

Not Medically Necessary:

Transcatheter ablation 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.

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.

When services may be Medically Necessary when criteria are met:

CPT	
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 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
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

When services are Not Medically Necessary:
For the procedure and diagnosis codes listed above when criteria are not met or for all other diagnoses not listed, or when the code describes a procedure or situation designated in the Clinical Indications section as not medically necessary.

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 12.1 million people in the United States will have AF by 2030, AF was the underlying cause of 26,535 deaths in 2019. The prevalence of AF in Americans younger than 65 years of age is 2%, while approximately 9% of adults 65 years and older (CDC, 2021) 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 among the other potential utility, can detect an episode of AF, but cannot terminate the episode. 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.

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 (PVI) 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 (PNP) 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 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.

According to the 2014 American Heart Association (AHA)/ American College of Cardiology (ACC)/ Heart Rhythm Society (HRS) guideline for the management of individuals with atrial fibrillation, the Society includes the following recommendations:

- For individuals with ***paroxysmal*** **AF**, transcatheter radiofrequency pulmonary vein ablation (PVA) may be considered*as an alternative* for individuals who are symptomatic and resistant to or unable to tolerate antiarrhythmic drug therapy.
- For symptomatic individuals with ***persistent*** **AF**, transcatheter PVA might be considered an alternative to individuals who are intolerant or refractory to antiarrhythmic drug therapy.

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.

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 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).
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> 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.

Wazni and colleagues (2021) reported results from a multicenter, randomized trial the STOP-AF First (Cryoballoon Catheter Ablation in Antiarrhythmic Drug Native Paroxysmal Atrial Fibrillation; NCT03118518) study that performed cryoballoon ablation as *initial* therapy for individuals with paroxysmal AF for which they had not received rhythm-control therapy. A total of 203 participants (18 to 80 years of age) were randomly assigned (1:1) to receive pulmonary vein isolation with cryoballoon (n=104, ablation group) versus treatment with antiarrhythmic drugs (n=99, drug therapy group). Participants received arrhythmia monitoring with 12-lead electrocardiography conducted at baseline and at 1, 3, 6 and 12 months; participant activated telephone monitoring conducted weekly and when symptoms were present. At 12 months the estimated treatment success was 74.6% (95% CI, 65.0 to 82.0) in the ablation group and 45% (95% CI, 34.6 to 54.7) in the drug-therapy group (P<0.001 by log-rank test). Within the 12 months there were two (1.9%) primary safety end-point events (pericardial effusion and myocardial infarction) in the ablation group. The number of individuals with serious adverse events was similar between the ablation group and the drug-therapy group. Among individuals randomly assigned to the drug-therapy group, 13% of participants discontinued treatment within 12 months and 34% underwent ablation within a year after randomization. The authors concluded that “cryoballoon ablation as initial therapy was superior to drug therapy for the prevention of atrial arrhythmia recurrence in patients with paroxysmal atrial fibrillation. Serious procedure-related adverse events were uncommon”

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 the overall goal of establishing the appropriate roles for medical and ablative intervention for AF. The study enrolled 2204 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.

Lo and colleagues (2021) reported results of a manufacturer sponsored, multi-center, single-arm trial, which evaluated the use of the TactiCath Contact Force Ablation Catheter, Sensor Enabled™ (TactiCath SE, Abbott Inc., Abbott Park, Illinois) for the treatment of drug-refractory, symptomatic paroxysmal AF in 156 individuals at 19 sites in the United States, Europe, and Australia. The primary safety outcome was the rate of device or procedure-related adverse events within 7 days. The primary efficacy outcome was success, defined as PVI at 30 minutes post-ablation. Two outcomes were prospectively captured:1-year freedom from recurrence of symptomatic AF, atrial flutter (AFL), and atrial tachycardia (AT) lasting > 30 seconds without a new or increased dose of Class I/III antiarrhythmic drugs; and 1-year drug-free success defined as the absence of any recurrent AF/AFL/AT lasting > 30 seconds without using Class I/III antiarrhythmic drugs. Exclusion criteria were persistent AF, implanted cardiac defibrillator, left atrial (LA) diameter > 5.0 cm, left ventricular ejection fraction < 35%, New York Heart Association (NYHA) functional class III or IV, body mass index > 40 kg/m2, and previous ablation therapy in the left atrium. There were 8 primary safety events in 7 out of 149 subjects (n=149). The analysis population included all individuals that had the device inserted except for 2 (1 withdrew from the trial before the 30-day visit without experiencing an event, and 1 missed the 30-day visit and did not experience an event). No primary safety events occurred beyond 30 days. The rate of significant device related events was 4.7% which was lower than the performance goal of 16.2% (p<0.0001). No strokes or transient ischemic attacks were reported. One incidence of deep venous thrombosis was related to the surgical removal of a circular mapping catheter, the investigated device was not involved in that event. The most common complication was cardiac tamponade, which occurred in 3 individuals. There was 1 case of atrio-esophageal fistula which was successfully treated with surgical intervention. No deaths were reported. The clinically relevant 1-year success rate was 82.2%, and 1-year drug-free success was 68.2%. The authors concluded that TactiCath SE device achieved performance goals set for safety and effectiveness.

Wu and colleagues (2021) reported a meta-analysis that assessed the efficacy and safety between second-generation cryoballoon (CB2) and contact force radiofrequency (CF-RF) using evidence from RCT’s. The primary outcome measured was absence of AT during the follow-up period. Secondary outcomes were procedure-related complications, procedure time and fluoroscopy time. Six RCTs with a total of 987 individuals were reviewed. No differences were found between CB2 and CF-RF in the absence of AT (relative risk [RR] = 1.03, p=0.616), or total procedural-related complications (RR = 1.25, p=0.457). CB2 treatment was associated with a higher risk of PNP than CF-RF (RR = 4.93, p=0.035). The occurrences of pericardial effusion/tamponade and vascular complications were comparable between the CB2 and CF-RF treatments (RR = 0.41, p=0.398; RR = 0.82, p=0.632), respectively. In addition, CB2 treatment had a shorter procedure time than CF-RF (weighted mean difference [WMD] = -20.75 min, p<0.001), whereas no difference was found in terms of fluoroscopy time (WMD = 4.63 min, p=0.179). The authors concluded that additional large-scale studies are needed to compare the clinical efficacy of the two techniques.

Razzack and colleagues (2022) reported a meta-analysis that included six RCTs, with 1212 individuals (Ablation n=609; Antiarrhythmic n=603), that examined whether early catheter ablation, as first-line therapy for AF is associated with improved clinical outcomes. The primary outcome measured was the first documented recurrence of any AT (symptomatic or asymptomatic; AF, AFL, and AT). Secondary outcomes included symptomatic AT and serious adverse events. The results demonstrated that individuals who underwent ablation were less likely to have recurrent AT compared to individuals that received antiarrhythmic drugs (p<0.00001).

Symptomatic AT was lower in the ablation group (p=0.01). No statistically significant differences were noted overall for any type of adverse events (p=0.64) and cardiovascular adverse events (p=0.65). The authors concluded that the efficacy and safety of catheter ablation (RFA and CBA) aimed at electrical PVI resulted in a lower recurrence rate of AT and maintenance of sinus rhythm, and that catheter ablation for AF rhythm control is superior to anti-arrhythmic drugs (AAD) in drug naïve individuals. Limitations of the meta-analysis included studies that differed in the use of Class I or III AADs, types of AF, and method of surveillance used to monitor recurrence, and a varied follow-up period (1–2 years). Five studies included individuals with paroxysmal AF only, therefore the data cannot be extrapolated to individuals with persistent AF. This meta-analysis also combined different ablation techniques, both RFA and CBA, to evaluate the primary efficacy. Additionally, the ablation targets beyond the pulmonary veins were at the treating providers discretion. Further large-scale studies with well controlled methodology are needed to compare the clinical efficacy of the techniques.

Kanagaratnam and colleagues (2023) reported a randomized, multi-center, open label trial (n=321) that compared whether a streamlined approach to AF using the AVATAR protocol of cryoballoon ablation without electrical mapping, and same day discharge achieved improved symptom control in individuals with paroxysmal AF, compared to AAD therapy over a 12-week period. One hundred ten individuals were assigned to the AVATAR protocol group, 103 individuals to the anti-arrhythmic group, and 108 individuals to the conventional ablation group. In the AVATAR-protocol ablation group, the Arctic Front Advance™ cryoballoon was used to occlude PVs. No intra-cardiac electrical recording catheters were deployed, and PVI was not formally assessed. A bedside transthoracic echocardiogram, hemoglobin check, and femoral puncture site assessment were completed 6 hours post-procedure. If stable, the individual was discharged on the day of intervention. In the AF ablation group, cryo-ablation efficacy was monitored with a circular mapping catheter. PVI was completed with either repeat CBA, deflectable cryotherapy catheter, or RF catheter. Post-procedural tests were the same as the AVATAR group, but individuals were discharged the next day. During the 12-week period, all pre-ablation anti-arrhythmic agents were continued for 4 weeks post-ablation and then reduced with the goal of cessation. Repeat ablations were required for individuals with symptoms due to recurrent AF from PV reconnection. A second ablation was performed at 10 weeks for recurrent AF symptoms, as part of the initial ablative treatment. In the drug therapy arm, individuals were assessed every 4 weeks to optimize anti-arrhythmics. Symptomatically improving individuals were discharged from hospital-based specialist arrhythmia care at 12 weeks. Individuals who had ongoing symptoms or problems related to their assigned therapy “failed 12-week discharge’ and counted as a primary endpoint. The results demonstrated that in the AVATAR group, 108 of 110 individuals (98%) underwent the planned ablation. Of these, 92 (84% of individuals randomized) were discharged the same day. Seventeen individuals (16%) were referred for a redo procedure at the 8-week review of whom 13 (12%) completed the procedure. Ninety-four individuals (85%) achieved symptom control and were discharged from specialist care at 12 weeks. In the anti-arrhythmic group, at 12 weeks, 47 individuals (46%) had achieved symptom control and were discharged from specialist hospital care, and 2 individuals had crossed over and completed ablation. In the conventional ablation group, 103 of 108 underwent the planned ablation (95%). Ninety-nine individuals had confirmed PVI (92%). Ten individuals (10%) were referred for a redo procedure at 8-week review. Ninety-seven individuals (90%) were discharged from specialist hospital care following review at 12 weeks. The hazard ratio (HR) for a primary endpoint event occurring when comparing AVATAR protocol group to drug therapy was 0.156, p<0.000. Twenty-three individuals (21%) recorded an endpoint event in the AVATAR group compared to 76 individuals (74%) within the drug therapy group. Comparing AVATAR and conventional ablation groups resulted in a non-significant HR of 1.173, p=0.61 with 23 individuals (21%) and 19 individuals (18%), respectively, recording primary endpoint events (p=0.61). The authors concluded that the AVATAR protocol was superior to drug therapy for avoiding hospital episodes related to AF treatment, but that conventional cryoablation was not superior to the AVATAR protocol.

Other Uses

Transcatheter radiofrequency ablation or cryoablation of arrhythmogenic foci in the pulmonary veins has also been evaluated to treat atrial flutter. 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. The cavotricuspid isthmus between the inferior vena cava and the tricuspid annulus (IVC-TA isthmus) is an obligatory route for typical atrial flutter and is considered the best anatomic target for ablation. However, researchers are assessing the hypothesis that the use of cryoballoon pulmonary vein isolation can achieve electrical disconnection between the pulmonary veins and the heart, resulting in higher rates of freedom from abnormal heart rhythms. An ongoing study evaluating cryoballoon pulmonary vein ablation as first-line treatment for typical atrial flutter (CRAFT) (NCT03401099) has an estimated enrollment of 130 participants and an estimated study completion date of December, 2023. 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. The evidence regarding the use of transcatheter radiofrequency ablation or cryoablation of arrhythmogenic foci in the pulmonary vein for the treatment of atrial flutter is currently insufficient to allow conclusions to be made.

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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Index

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
Reviewed	08/10/2023	Medical Policy & Technology Assessment Committee (MPTAC) review. Updated Discussion, References and Websites sections.
Reviewed	08/11/2022	MPTAC review. Updated Discussion, References and Websites sections.
	12/29/2021	Updated Coding section with 01/01/2022 CPT changes to descriptor for code 93656.
Revised	08/12/2021	MPTAC review. *Title changed to: Transcatheter Ablation of Arrhythmogenic Foci in the Pulmonary Veins.* Clarified MN statement to address transcatheter “ablation” of arrhythmogenic foci in the pulmonary veins as a treatment of symptomatic individuals when criteria met. Combined NMN statements to address transcatheter ablation of arrhythmogenic foci in the pulmonary veins when the medically necessary criteria are not met and for all other indications. Updated Description, Coding, Discussion, References and Websites sections.
Reviewed	05/13/2021	MPTAC review. Updated Description, Discussion, References and Websites sections. Reformatted Coding section.

Revised	05/14/2020	MPTAC review. Revised MN clinical indications for transcatheter radiofrequency ablation or cryoablation of arrhythmogenic foci in the pulmonary veins in the treatment of atrial fibrillation, Persistent AF includes criteria for individuals refractory or intolerant to one or more antiarrhythmic drugs (or has a contraindication to all appropriate antiarrhythmic drug therapy). Clarified MN criteria for first-line therapy for *paroxysmal* AF, as an alternative to medical therapy and revised the MN criteria for symptomatic *persistent* AF, with the addition of medication treatment failure when refractory or intolerant to antiarrhythmic drugs, prior to ablation or cryoablation of arrhythmogenic foci in the pulmonary vein. Updated Discussion, References and Websites sections.
	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	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.
