WELLPOINT

Medical Policy

Subject:	Transcatheter Radiofrequency Ablation of Arrhythmogenic Foci in the Pulmonary Veins as a Treatment of Atrial Fibrillation		
Policy #:	MED.00064	**Current Effective Date:**	12/01/2005
Status:	New	**Last Review Date:**	12/01/2005

DRAFT

Description/Scope

Atrial fibrillation (AF) is the most common sustained cardiac arrhythmia. A variety of ablative procedures have been investigated to treat this condition. The policy addresses transcatheter radiofrequency ablation of arrhythmogenic foci in the pulmonary veins for the treatment of atrial fibrillation.

Policy Statement

Medically Necessary:

Transcatheter radiofrequency ablation of arrhythmogenic foci in the pulmonary veins is considered **medically necessary** as a treatment of atrial fibrillation when the patient:

- Is **symptomatic**; **AND**
- Is resistant to two (2) or more antiarrhythmic drugs (or has intolerance of or a contraindication to appropriate antiarrhythmic drug therapy).

Investigational/Not Medically Necessary:

Transcatheter radiofrequency ablation of arrhythmogenic foci in the pulmonary veins is considered **investigational/not medically necessary** as a treatment of atrial fibrillation in **ANY** of the following circumstances:

- As a **first-line** treatment of atrial fibrillation,
- In the **absence** of resistance to two (2) or more antiarrhythmic drugs (including the absence of intolerance or contraindication to appropriate antiarrhythmic drug therapy),
- **Asymptomatic** atrial fibrillation.

Rationale

For individuals with paroxysmal atrial fibrillation, pulmonary vein ablation (PVA) may be considered an alternative to drug therapy. For individuals with persistent AF, it might be considered an alternative to either drug or defibrillator therapy. For individuals with permanent AF, pulmonary vein ablation may be considered an alternative either to drug therapy or ablation of the AV node followed by ventricular pacing. For all types of AF, it is possible that pulmonary vein ablation may not be curative as a sole treatment, but might alter the underlying myocardial triggers or substrate in such a way that subsequent pharmacologic therapy may become more effective.

The published literature on 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

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included only patients 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 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, continue to be refined, the numbers of patients treated by catheter ablation worldwide and reported to surveyors (Cappato R et al. Circulation, 2005) are large with an increasing percentage undergoing PVA in preference to other techniques (6,600 of 10,199 in 2002). While the survey recognizes the variation in mapping and procedural techniques utilized, an average of 52% patients 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 B and Haines DE, analyzed 19 trials including 2,148 patients undergoing focal ablation and pulmonary vein isolation or linear ablation (compartmentalization) of the right atrium with or without left atrium. Of these patients, 1.991 underwent either focal ablation or isolation of pulmonary veins. Although the majority had paroxysmal atrial fibrillation (AF), patients with persistent AF were also included and had failed previous antiarrhythmic drug therapy. For the patients 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 C and colleagues, in a non randomized study of 1,171patients with symptomatic AF, compared outcomes of PVA in 589 patients with antiarrhythmic therapy in 582 patients 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 patients with symptomatic AF.

Although most reports involve the use of PVA in patients with AF who remain symptomatic despite drug therapy, a recent small pilot study by Wazni OM and colleagues in JAMA, June 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 one-year follow up period, the authors acknowledge the sample size (70 patients) and one year follow-up period were not adequate to assess therapeutic effects on certain important outcomes such as stroke. Also, that 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.

The majority of studies have involved patients with symptomatic AF. Randomized trials have not demonstrated improved outcomes resulting from pharmacological rhythm control versus rate control of AF. While these findings cannot necessarily be extrapolated to rhythm control using ablative techniques (partly because the use of antiarrhythmic drugs has been associated with increased mortality and partly based on different characteristics of patients undergoing PVA), there is currently inadequate data to support improved outcomes utilizing PVA versus rate control for asymptomatic patients with AF.

Background/Overview

Atrial fibrillation has a prevalence estimated at 0.4% of the population and increases with age. The underlying mechanism of AF involves interplay between electrical triggering events and the myocardial substrate that permits

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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 (e.g., 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 patients 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 atrial fibrillation 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 cardio version, 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 defibrillators are contraindicated for individuals with permanent AF.

The above treatment options are not considered curative. A variety of ablative procedures have been investigated 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 by modifying the triggers of AF and/or the myocardial substrate that maintains the aberrant rhythm. 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 atrial fibrillation, 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 with in the pulmonary veins, as identified by electrophysiologic mapping; segmental ostial ablation guided by pulmonary vein potential

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(electrical approach); or circumferential pulmonary vein ablation (anatomic approach). Circumferential pulmonary vein ablation appears to be the preferred approach at this time.

Definitions

Arrhythmogenic: producing or promoting arrhythmia

Atrial fibrillation: a condition where there is disorganized electrical conduction in the atria, resulting in ineffective pumping of blood into the ventricle

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

Myocardial substrate: myocardial cells that are capable of receiving and responding to electrical impulses

Coding

The following codes for treatments and procedures applicable to this policy 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

	No specific code

ICD-9 Procedure

	No specific code

ICD-9 Diagnosis

427.31	Atrial fibrillation

When services are Investigational/Not Medically Necessary:

For codes listed above, for all other diagnoses not listed; or when the code describes a procedure indicated in the Policy section as Investigational/Not Medically Necessary.

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Peer Reviewed Publications:

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16. Pappone C, Santinelli V, Manguso F, et al. Pulmonary vein denervation enhances long-term benefit after circumferential ablation for paroxysmal atrial fibrillation. Circulation. 2004; 109(3):327-334.
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Government Agency, Medical Society, and Other Authoritative Publications:

1. ACC/AHA/ESC Guidelines for the Management of Patients with Atrial Fibrillation. http://www.acc.org/clinical/guidelines/atrial%5Ffib/exec%5Fsumm/exec%5Ffigures.htm. Accessed August 5, 2005.

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Policy History

Status	Date	Action
New	12/01/2005	Medical Policy & Technology Assessment Committee (MPTAC) initial policy development

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