

Protocol

Catheter Ablation of the Pulmonary Veins as Treatment for Atrial Fibrillation

(20219)

Medical Benefit		Effective Date: 07/01/12	Next Review Date: 03/15
Preauthorization	No	Review Dates: 05/09, 03/10, 03/11, 03/12, 03/13, 03/14	

*The following Protocol contains medical necessity criteria that apply for this service. It is applicable to Medicare Advantage products unless separate Medicare Advantage criteria are indicated. If the criteria are not met, reimbursement will be denied and the patient cannot be billed. **Preauthorization is not required.** Please note that payment for covered services is subject to eligibility and the limitations noted in the patient's contract at the time the services are rendered.*

Description

Radiofrequency ablation using a percutaneous catheter-based approach is widely used to treat supraventricular arrhythmias. Atrial fibrillation frequently arises from an abnormal focus at or near the junction of the pulmonary veins and the left atrium, thus leading to the feasibility of more focused ablation techniques directed at these structures. Catheter-based ablation, using both radiofrequency ablation and cryoablation, is being studied in the treatment of various types of atrial fibrillation.

Background

Atrial fibrillation is the most common cardiac arrhythmia, with a prevalence estimated at 0.4% of the population, increasing with age. The underlying mechanism of atrial fibrillation involves an 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 atrial fibrillation appears to be located within the cardiac muscle that extends into the pulmonary veins.

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

Atrial fibrillation can be subdivided into three types:

- paroxysmal (episodes that last fewer than seven days and are self-terminating),
- persistent (episodes that last for more than seven days and can be terminated pharmacologically or by electrical cardioversion), or
- permanent.

Treatment strategies can be broadly subdivided into rate control, in which only the ventricular rate is controlled and the atria are allowed to fibrillate, or rhythm control, in which there is an attempt to re-establish and maintain normal sinus rhythm. Rhythm control has long been considered an important treatment goal for management of atrial fibrillation, although its primacy has recently been challenged by the results of several

randomized trials that reported that pharmacologically maintained rhythm control offered no improvement in mortality or cardiovascular morbidity compared to rate control.

Currently, the main indications for a rhythm control are for patients with paroxysmal or persistent atrial fibrillation who have hemodynamic compromise associated with episodes of atrial fibrillation or who have bothersome symptoms despite adequate rate control. A rhythm-control strategy involves initial pharmacologic or electronic cardioversion, followed by pharmacologic treatment to maintain normal sinus rhythm. However, antiarrhythmic medications are often not effective in maintaining sinus rhythm. As a result, episodes of recurrent atrial fibrillation are typical, and patients with persistent atrial fibrillation may require multiple episodes of cardioversion. Implantable atrial defibrillators, which are designed to detect and terminate an episode of atrial fibrillation, are an alternative in patients otherwise requiring serial cardioversions, but these have not yet achieved widespread use. Patients with paroxysmal atrial fibrillation, by definition, do not require cardioversion but may be treated pharmacologically to prevent further arrhythmic episodes.

Treatment of permanent atrial fibrillation 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 entail lifelong anticoagulation (due to the ongoing fibrillation of the atria), loss of AV synchrony, and lifelong pacemaker dependency. Implantable defibrillators are contraindicated in patients with permanent atrial fibrillation.

The cited treatment options are not considered curative. A variety of ablative procedures have been investigated as potentially curative approaches, or perhaps modifying the arrhythmia such that drug therapy becomes more effective. Ablative approaches focus on interruption of the electrical pathways that contribute to atrial fibrillation through modifying the arrhythmia triggers and/or the myocardial substrate that maintains the aberrant rhythm. The Maze procedure, an open surgical procedure often combined with other cardiac surgeries (i.e., valve repair), is an ablative procedure that involves sequential atriotomy incisions designed to create electrical barriers that prevent the maintenance of atrial fibrillation. Because of the highly invasive nature of this procedure, it is currently mainly reserved for patients who are undergoing open heart surgery for other reasons, such as valve repair or coronary artery bypass grafting.

Radiofrequency ablation using a percutaneous catheter-based approach is a widely used technique for a variety of supraventricular arrhythmias, in which intracardiac mapping identifies a discrete arrhythmogenic focus that is the target of ablation. The situation is more complex for atrial fibrillation, since there is not a single arrhythmogenic focus. Since the inception of ablation techniques in the early 1990s, there has been a progressive understanding of the underlying electrical pathways in the heart that are associated with atrial fibrillation. In the late 1990s, it was recognized that atrial fibrillation most frequently arose from an abnormal focus at or near the junction of the pulmonary veins and the left atrium, thus leading to the feasibility of more focused, percutaneous ablation techniques. The basic strategies that have emerged for focal ablation within the pulmonary veins, as identified by electrophysiologic mapping, are segmental ostial ablation guided by pulmonary vein potential (electrical approach), or circumferential pulmonary vein ablation (anatomic approach). Circumferential pulmonary vein ablation is the most commonly used approach at the present time. The procedure also can be done using cryoablation technology.

Repeat procedures following an initial radiofrequency ablation are commonly performed if atrial fibrillation recurs or if atrial flutter develops post-procedure. The need for repeat procedures may, in part, depend on clinical characteristics of the patient (age, persistent vs. paroxysmal atrial fibrillation, atrial dilatation, etc.), and the type of initial ablation performed. Repeat procedures are generally more limited than the initial procedure. For example, in cases where electrical reconnections occur as a result of incomplete ablation lines, a “touch up” procedure is done to correct gaps in the original ablation. In other cases where atrial flutter develops following ablation, a “flutter ablation” is performed, which is more limited than the original atrial fibrillation ablation.

procedure. A number of clinical and demographic factors have been associated with the need for a second procedure, including age, length of atrial fibrillation, permanent atrial fibrillation, left atrial size, and left ventricular ejection fraction.

Regulatory Status

In February 2009, the NAVISTAR® THERMOCOOL® Irrigated Deflectable Diagnostic/Ablation Catheter and EZ Steer ThermoCool NAV Catheter (Biosense Webster Inc.) were approved by the U.S. Food and Drug Administration (FDA) through the pre-market approval (PMA) process for “catheter-based cardiac electrophysiological mapping (stimulating and recording), and when used with the Stockert 70 generator, for the treatment of: a) Type I atrial flutter in patients age 18 or older; b) recurrent drug/device refractory sustained monomorphic ventricular tachycardia (VT) due to prior myocardial infarction (MI) in adults; c) drug refractory recurrent symptomatic paroxysmal atrial fibrillation, when used with compatible three-dimensional electroanatomic mapping systems.” (For radiofrequency ablation)

In December 2010, Medtronic’s Arctic Front® Cardiac CryoAblation Catheter and CryoConsole were approved by the FDA for the “treatment of drug refractory recurrent symptomatic paroxysmal atrial fibrillation.” In addition, Medtronic’s Freezor® MAX Cardiac CryoAblation Catheter was approved as an adjunctive device to be used in conjunction with the Arctic Front system for “gap cryoablation to complete electrical isolation of the pulmonary veins, cryoablation of focal trigger sites, and creation of ablation line between the inferior vena cava and the tricuspid valve.” (For cryoablation)

In addition, the FDA has also granted PMA approval to numerous catheter ablation systems for other ablation therapy for arrhythmias such as supraventricular tachycardia, atrial flutter, and ventricular tachycardia.

Related Protocols

Catheter Ablation for Cardiac Arrhythmias

Open and Thoracoscopic Approaches to Treat Atrial Fibrillation (Maze and Related Procedures)

Policy (Formerly Corporate Medical Guideline)

Transcatheter radiofrequency ablation of arrhythmogenic foci in the pulmonary veins may be considered **medically necessary** as a treatment for either of the following indications which have failed to respond to adequate trials of antiarrhythmic medications:

- Symptomatic paroxysmal or symptomatic persistent atrial fibrillation or
- As an alternative to atrioventricular nodal ablation and pacemaker insertion in patients with class II or III congestive heart failure and symptomatic atrial fibrillation.

Repeat radiofrequency ablations may be considered **medically necessary** in patients with recurrence of atrial fibrillation and/or development of atrial flutter following the initial procedure. (See Policy Guidelines)

Transcatheter ablation of arrhythmogenic foci in the pulmonary veins as a treatment is considered **investigational** as a treatment for all indications except for specific cases of atrial fibrillation as noted above.

Transcatheter cryoablation of arrhythmogenic foci in the pulmonary veins as a treatment for atrial fibrillation is considered **investigational**.

Policy Guideline

Circumferential ablation of the pulmonary vein might be considered basically intra-arterial in location due to its

close proximity to the pulmonary os and atria. Supraventricular tachycardias typically describe arrhythmias due to accessory pathways within the atria, such as Wolff-Parkinson-White syndrome or atrioventricular nodal reentry arrhythmias. Although not consistently associated with tachycardia, strictly speaking atrial fibrillation could be considered a type of supraventricular tachycardia.

As many as 30% of patients will require a follow-up (repeat) procedure due to recurrence of atrial fibrillation or to developing atrial flutter. In most of the published studies, success rates were based on having as many as three separate procedures, although these repeat procedures may be more limited than the initial procedure.

Services that are the subject of a clinical trial do not meet our Technology Assessment Protocol criteria and are considered investigational. *For explanation of experimental and investigational, please refer to the Technology Assessment Protocol.*

It is expected that only appropriate and medically necessary services will be rendered. We reserve the right to conduct prepayment and postpayment reviews to assess the medical appropriateness of the above-referenced procedures. **Some of this Protocol may not pertain to the patients you provide care to, as it may relate to products that are not available in your geographic area.**

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We are not responsible for the continuing viability of web site addresses that may be listed in any references below.

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