

Corporate Medical Policy

Transcatheter Ablation of Arrhythmogenic Foci in the Pulmonary Vein

File Name:	transcather_ablation_of_arrhythmogenic_foci_in_the_pulmonary_vein
Origination:	11/2004
Last CAP Review:	6/2010
Next CAP Review:	6/2012
Last Review:	6/2010

Description of Procedure or Service

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 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 paroxysmal (episodes that last fewer than 7 days and are self-terminating), persistent (episodes that last for more than 7 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 reestablish and maintain normal sinus rhythm. Rhythm control has long been considered an important treatment goal for atrial fibrillation management, 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 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, may be 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

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episodes.

Treatment of permanent atrial fibrillation, by definition, 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 triggers of atrial fibrillation 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 involving 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 reserved mainly for patients who are undergoing open heart surgery for other reasons, such as valve repair or coronary artery bypass grafting. (Please see the BCBSNC Evidence Based Guideline titled, "Maze Procedure for Atrial Fibrillation or Flutter).

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.

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 patients (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.

******Note: This Medical Policy is complex and technical. For questions concerning the technical language and/or specific clinical indications for its use, please consult your physician.***

Policy

BCBSNC will provide coverage for Transcatheter Ablation of Arrhythmogenic Foci in the Pulmonary Vein when it is determined to be medically necessary because the medical criteria and guidelines shown below are met.

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Benefits Application

This medical policy relates only to the services or supplies described herein. Please refer to the Member's Benefit Booklet for availability of benefits. Member's benefits may vary according to benefit design; therefore member benefit language should be reviewed before applying the terms of this medical policy.

When Transcatheter Ablation of Arrhythmogenic Foci in the Pulmonary Vein is covered

Transcatheter radiofrequency ablation of arrhythmogenic foci in the pulmonary veins as a treatment for atrial fibrillation may be considered medically necessary for the following indications:

- patients with symptomatic paroxysmal or persistent atrial fibrillation, who have failed antiarrhythmic medications, as an alternative to continued medical management; or
- patients with class II or III congestive heart failure and symptomatic atrial fibrillation in whom heart rate is poorly controlled by standard medications, as an alternative to atrioventricular nodal ablation and pacemaker insertion.

When Transcatheter Ablation of Arrhythmogenic Foci in the Pulmonary Vein is not covered

Transcatheter ablation of arrhythmogenic foci in the pulmonary veins as a treatment for atrial fibrillation is considered investigational for all other indications.

Policy Guidelines

In patients with paroxysmal or persistent atrial fibrillation, pulmonary vein ablation may be considered an alternative to drug therapy. In patients with permanent atrial fibrillation, pulmonary vein ablation may be considered an alternative to drug therapy or to atrioventricular (AV) nodal ablation and pacing. For all types of atrial fibrillation, 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.

A variety of outcomes for treatment of atrial fibrillation may be considered. The mortality and morbidity related to atrial fibrillation, such as cardiovascular mortality, stroke, and congestive heart failure, are the most important clinical outcomes. However, these are uncommon events and currently available trials are not powered to detect differences in these outcomes. Quality of life is also an important outcome, as these measures reflect important manifestations of atrial fibrillation such as symptoms and reduced exercise tolerance. Atrial fibrillation has been shown to be associated with lower quality of life (QOL) scores, and maintenance of sinus rhythm has been associated with higher QOL scores for patients with paroxysmal atrial fibrillation.

Recurrence of atrial fibrillation is a more problematic outcome measure, since the intermittent and often transient nature of recurrences makes accurate measurement difficult. This outcome measure has been reported in different ways. For example, the proportion of patients in sinus rhythm at the end of the study, the time to first recurrence, and the number of recurrences within a time period have been reported. A recent publication highlights the difficulties in measuring atrial fibrillation recurrence and recommends a measure of atrial fibrillation "burden", defined as the percentage of time an individual is in atrial fibrillation, as the optimal measure of treatment efficacy. However, this parameter requires continuous monitoring over a relatively long period of time, which is

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inconvenient for patients, resource intensive and usually not pragmatic in patients who do not already have an implanted pacemaker.

Recommendations for outcome assessment in trials of atrial fibrillation treatment were included in the 2006 American College of Cardiology/American Heart Association practice guidelines for the treatment of atrial fibrillation. These guidelines pointed out that the appropriate endpoints for evaluation of treatment efficacy in patients with paroxysmal and persistent atrial fibrillation have little in common. For example, in studies of persistent atrial fibrillation, the proportion of patients in sinus rhythm at the end of follow-up is a useful end point, but this is a less useful measure in studies of paroxysmal atrial fibrillation. Given all these variables, ideally, controlled clinical trials would report a range of outcomes (including QOL) and complications in homogeneous patient groups and compare to the most relevant treatment alternatives, such as pharmacologic therapy, defibrillator therapy, and AV nodal ablation, depending on the classification of atrial fibrillation (paroxysmal, persistent, or permanent).

Underlying these issues in outcome measurement is the ongoing controversy regarding the relative benefits of rhythm versus rate control. Randomized trials of pharmacologic therapies have not demonstrated the superiority of rhythm versus rate control. However, the apparent equivalency of these two strategies with pharmacologic therapy cannot be extrapolated to the rhythm control achieved with ablation. Antiarrhythmic medications used for rhythm control are only partially effective, and have serious complications, including proarrhythmic properties that can be lethal. Therefore, nonpharmacologic strategies for rhythm control have the potential to achieve superior outcomes than have been seen with pharmacologic strategies.

The evidence reviewed for this policy update is based on a 2008 TEC Assessment. The Assessment concluded that radiofrequency catheter ablation is more effective than medications in maintaining sinus rhythm across a wide spectrum of patients with atrial fibrillation, and across different variations of catheter ablation. The evidence on QOL was suggestive of a benefit for patients undergoing catheter ablation, but not definitive. For other outcomes, the evidence did not permit conclusions. It was not possible to estimate the rate of serious complications, such as pulmonary vein stenosis, cardiac tamponade, or atrio-esophageal fistula with precision, given the limited number of patients in the trials and the continued evolution of the technique. However, the rate of serious complications is expected to be low, likely in the 1%–3% range.

Based on these findings, TEC criteria were met for 2 indications: patients with symptomatic paroxysmal or persistent atrial fibrillation, who have failed treatment with antiarrhythmic drugs; and patients with symptomatic atrial fibrillation and congestive heart failure, who have failed treatment with standard medications for rate control and who would otherwise be considered for AV nodal ablation and pacemaker insertion. For the first indication, the conclusion followed from the premise that reducing episodes of recurrent atrial fibrillation for this population will reduce or eliminate the symptoms associated with episodes of atrial fibrillation. For the other indication, the single multicenter randomized, controlled trial available was judged sufficient to conclude that catheter ablation improved outcomes compared to the alternative, AV nodal ablation and pacemaker insertion. While this trial was relatively small, it was judged to be otherwise of high quality and reported improvements of a relatively large magnitude across a range of clinically important outcome measures, including QOL, exercise tolerance, left ventricular ejection fraction, and maintenance of sinus rhythm.

In summary, the evidence is sufficient to conclude that radiofrequency catheter ablation is more effective than pharmacologic therapy in maintaining sinus rhythm. For patients with symptomatic atrial fibrillation who have failed antiarrhythmic medications, maintenance of sinus rhythm will lead to an improvement in symptoms and therefore will improve outcomes. For the larger population of patients with atrial fibrillation whose symptoms are adequately controlled by rate control, the evidence is not sufficient to conclude that outcomes are improved. For the small subset of patients with atrial fibrillation and congestive heart failure, in whom standard medications for atrial fibrillation have failed to adequately control ventricular rate, the evidence is sufficient to

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conclude that radiofrequency catheter ablation improves outcomes compared to the alternative, AV nodal ablation and pacemaker insertion.

Billing/Coding/Physician Documentation Information

This policy may apply to the following codes. Inclusion of a code in this section does not guarantee that it will be reimbursed. For further information on reimbursement guidelines, please see Administrative Policies on the Blue Cross Blue Shield of North Carolina web site at www.bcbsnc.com. They are listed in the Category Search on the Medical Policy search page.

Applicable codes: There is currently no specific code for Transcatheter Ablation of Arrhythmogenic Foci in the Pulmonary Veins. Services should be submitted in the form on an unlisted code. Medical records for the explanation of the service rendered may be necessary.

CPT code 93651 includes ablation of intraatrial arrhythmogenic foci as treatment of a supraventricular tachycardia. Circumferential ablation of the pulmonary vein might be considered basically intraarterial in location due to its close proximity of the pulmonary os and atria. Supraventricular tachycardias typically describe arrhythmias due to accessory pathways within the atria, such as Wolff-Parkinson-White syndrome or AV nodal reentry arrhythmias. Although not consistently associated with tachycardia, strictly speaking atrial fibrillation could be considered a type of supraventricular tachycardia

BCBSNC may request medical records for determination of medical necessity. When medical records are requested, letters of support and/or explanation are often useful, but are not sufficient documentation unless all specific information needed to make a medical necessity determination is included.

Scientific Background and Reference Sources

ACC/AHA/ESC Guidelines for the management of patients with atrial fibrillation. (2001). Retrieved on October 28, 2004 from http://www.acc.org/clinical/guidelines/atrial%5Ffib/exec%5Fsumm/pdfs/AFexecsumm8_30.pdf.

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Specialty Matched Consultant Advisory Panel - 11/2005.

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National Institute for Clinical Excellence (NICE). Percutaneous radiofrequency ablation for atrial fibrillation. Interventional Procedure Guidance 168. London, UK: NICE; April 2006. Retrieved 7/23/07 from <http://guidance.nice.org.uk/IPG168/guidance/pdf/English/download.dsp>

Fuster V, Ryden LE, Cannom DS, et al. ACC/AHA/ESC 2006 guidelines for the management of patients with atrial fibrillation: a report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines and the European Society of Cardiology Committee for Practice Guidelines (Writing Committee to Revise the 2001 Guidelines for the Management of Patient with Atrial Fibrillation). *J Am Coll Cardiol*. 2006; 48:e149-e246. Retrieved 7/23/07 from [http://www.acc.org/qualityand science/clinical/guidelines/atrial_fib/pdfs/AF_Full_Text.pdf](http://www.acc.org/qualityand%20science/clinical/guidelines/atrial_fib/pdfs/AF_Full_Text.pdf)

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BCBSA TEC Assessment. Vol. 23, No. 11. April 2009.

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BCBSA Medical Policy Reference Manual [Electronic Version]. 2.02.19, 1/08/09

BCBSA Medical Policy Reference Manual [Electronic Version]. 2.02.19, 8/13/09

Specialty Matched Consultant Advisory Panel 6/2010

Policy Implementation/Update Information

11/11/04 New policy issued. Transcatheter ablation of arrhythmogenic foci in the pulmonary vein is considered investigational. References added. Notification 11/11/2004. Effective 1/20/2005.

11/17/05 Specialty Matched Consultant Advisory Panel review 11/07/05. No change in policy.

6/4/07 Policy number changed from RAD5159 to RAD5189. (adn)

11/19/07 References updated. Specialty Matched Consultant Advisory Panel review meeting 10/29/07. No change to policy statement.

7/20/09 Description section revised. Policy statement changed to read: BCBSNC will provide coverage for Transcatheter Ablation of Arrhythmogenic Foci in the Pulmonary Vein when it is determined to be medically necessary because the medical criteria and guidelines shown below are met. Information in the When Covered section deleted and replaced with the following: "Transcatheter radiofrequency ablation of the pulmonary veins as a treatment for atrial fibrillation (AF) may be considered medically necessary for the following indications: patients with symptomatic paroxysmal or persistent atrial fibrillation, who have failed antiarrhythmic medications, as an alternative to continued medical management; or patients with class II or III congestive heart failure and symptomatic AF in whom heart rate is poorly controlled by standard medications, as an alternative to atrioventricular nodal ablation and pacemaker insertion." Information in the When Not Covered section deleted and replaced with the following: "Transcatheter ablation of the pulmonary veins as a treatment for atrial fibrillation (AF) is considered investigational for all other indications." Policy Guidelines revised. References updated. (adn)

12/7/09 Information regarding repeat procedures added to the Description Section. Specialty Matched Consultant Advisory Panel review 10/30/09. No change to policy statement or coverage criteria. (adn)

8/3/10 Specialty Matched Consultant Advisory Panel review 6/2010. Medical Policy number removed. No changes in policy statement.(mco)

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