Catheter Ablation as a Treatment for Atrial Fibrillation

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.

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, e.g., 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
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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 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 (e.g., 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.

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 using radiofrequency energy is the most commonly used approach at the present time. The procedure also can be done using cryoablation technology. Use of currently-available catheters for atrial fibrillation ablation has a steep learning curve because they require extensive guiding to multiple ablation points. One of the potential advantages to cryoablation techniques is that cryoablation catheters have a circular or shaped endpoint, allowing a “one-shot” ablation. Other types of radiofrequency catheters, such as Medtronic’s radiofrequency-based Pulmonary Vein Ablation Catheter®, that incorporate circular or otherwise shaped endpoints are under investigation.

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.
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Regulatory Status

In February 2009, the NAISTAR® 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 policies:
Percutaneous Left Atrial Appendage Closure Device for Stroke Prevention

***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 catheter ablation as a treatment for atrial fibrillation when it is determined to be medically necessary because the medical criteria and guidelines shown below are met.

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 Catheter Ablation as a Treatment for Atrial Fibrillation is covered

Transcatheter radiofrequency ablation or cryoablation to treat atrial fibrillation may be considered medically necessary for the following indications:

- patients with symptomatic paroxysmal or persistent atrial fibrillation, or
- patients with class II or III congestive heart failure and symptomatic atrial fibrillation as an alternative to atroventricular nodal ablation and pacemaker insertion.

Transcatheter radiofrequency ablation or cryoablation to treat atrial fibrillation may be considered
Catheter Ablation as a Treatment for Atrial Fibrillation

Medically necessary as an initial treatment for patients with symptomatic paroxysmal atrial fibrillation in whom a rhythm-control strategy is desired.

Repeat radiofrequency ablations or cryoablation may be considered medically necessary in patients with recurrence of atrial fibrillation and/or development of atrial flutter following the initial procedure.

When Catheter Ablation as a Treatment for Atrial Fibrillation is not covered

Transcatheter ablation to treat atrial fibrillation is considered investigational for all other indications not listed above.

Policy Guidelines

There is not one single procedure for catheter ablation, but several variations. Electrical isolation of the pulmonary vein musculature (pulmonary vein isolation) is the cornerstone of most atrial fibrillation ablation procedures, but additional ablation sites may also be included during the initial ablation. Potential additional ablation procedures include: creation of linear lesions within the left atrium; ablation of focal triggers outside the pulmonary veins; ablation of areas with complex fractionated atrial electrograms; and ablation of left atrial ganglionated plexi. The specific ablation sites may be determined by electroanatomical mapping to identify additional sites of excitation. As a result, sites may vary from patient to patient, even if they are treated by the same physician. Patients with longstanding persistent atrial fibrillation may need more extensive ablation. Similarly, repeat ablation procedures for recurrent atrial fibrillation generally involve more extensive ablation than do initial procedures.

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 3 separate procedures, although these repeat procedures may be more limited than the initial procedure.

Results of randomized, controlled trials that compare radiofrequency ablation with antiarrhythmic medications report that freedom from atrial fibrillation is more likely following ablation compared with medications. Results of long-term follow-up of 5 to 6 years following ablation demonstrate that late recurrences continue to occur in patients who are free of atrial fibrillation at 1 year. However, the majority of patients who are atrial-fibrillation-free at 1 year remain atrial-fibrillation-free at 5 to 6 years. Rates of complications following ablation remain somewhat uncertain. Death is rare, and a 2013 systematic review including over 83,000 patients reported a major complication rate of 2.9%. The available evidence is sufficient to draw conclusions and to determine that outcomes are improved with the use of catheter ablation of arrhythmogenic foci or to electrically isolate the pulmonary veins for symptomatic paroxysmal or persistent atrial fibrillation, when antiarrhythmic medications have failed to adequately control symptoms.

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: 93653, 93654, 93655, 93656, 93657
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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


Luik A, Merkel M, Hoeren D et al. Rationale and design of the FreezeAF: a randomized controlled noninferiority trial comparing isolation of the pulmonary veins with the cryoballoon catheter versus open irrigated radiofrequency ablation in patients with paroxysmal atrial fibrillation. Am Heart J 2010; 159(4):555-60.e1.


For policy re-titled Catheter Ablation of the Pulmonary Veins as Treatment for Atrial Fibrillation


Catheter Ablation as a Treatment for Atrial Fibrillation

Medical Director review 5/2011


Specialty Matched Consultant Advisory Panel review 6/2012


Catheter Ablation as a Treatment for Atrial Fibrillation

2014.


Specialty Matched Consultant Advisory Panel review 6/2014
Medical Director review 6/2014
Specialty Matched Consultant Advisory Panel review 6/2015
Medical Director review 6/2015

Policy Implementation/Update Information


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)

Catheter Ablation as a Treatment for Atrial Fibrillation

11/9/10 Added cryoablation technology information to Description section and Policy Guidelines section. References updated. Added the following statement to When Not Covered section: “Transcatheter cryoablation of the pulmonary veins as a treatment for atrial fibrillation is considered investigational.”

For policy re-titled Catheter Ablation of the Pulmonary Veins as Treatment for Atrial Fibrillation

5/24/11 Policy re-titled. “When Covered” section revised. Previous criteria required failure of medical management prior to treatment with transcatheter ablation. The new criteria are as follows: “patients with symptomatic paroxysmal or persistent atrial fibrillation, or patients with class II or III congestive heart failure and symptomatic atrial fibrillation as an alternative to atroventricular nodal ablation and pacemaker insertion. 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.” References updated. Policy Guidelines updated. Medical Director review 5/2011. (mco)

7/19/11 Specialty Matched Consultant Advisory Panel review 6/2011. No changes to policy statements. (mco)

5/1/12 References updated. No changes to policy statements. (mco)


1/1/13 Added new CPT codes to Billing/Coding section: 93653, 93654, 93655, 93656, 93657. Deleted CPT code 93651 and information regarding use of unlisted code for these services from the Billing/Coding section. Added related policy to Description section. No changes to Policy Statements. (mco)


For policy re-titled Catheter Ablation as Treatment for Atrial Fibrillation

7/15/14 Policy re-titled from “Catheter Ablation of the Pulmonary Veins as Treatment for Atrial Fibrillation” to “Catheter Ablation as a Treatment for Atrial Fibrillation”. Description section updated. All references specific to ablation of “pulmonary veins” deleted from policy. “Transcatheter Radiofrequency Ablation” revised to “Transcatheter Ablation” in the “When Covered” section. The following statement removed from the “When not Covered” section: “Transcatheter cryoablation as a treatment for atrial fibrillation is considered investigational.” Policy Guidelines revised. References updated. Medical Director review 6/2014. Specialty Matched Consultant Advisory Panel review 6/2014. (mco)

9/1/15 Specialty Matched Consultant Advisory Panel review 6/24/2015. Medical Director review 6/2015 When Covered section revised to include cryoablation as initial treatment for paroxysmal atrial fibrillation. When Not Covered section updated. Policy Guidelines section updated. References updated. (td)

Medical policy is not an authorization, certification, explanation of benefits or a contract. Benefits and eligibility are determined before medical guidelines and payment guidelines are applied. Benefits are determined by the group contract and subscriber certificate that is in effect at the time services are rendered. This document is solely provided for informational purposes only and is based on research of current medical literature and review of common medical practices in the treatment and diagnosis of disease. Medical practices and knowledge are constantly changing and BCBSNC reserves the right to review and revise its medical policies periodically.