Catheter Ablation as a Treatment for Atrial Fibrillation

Radiofrequency ablation (RFA) using a percutaneous catheter is a common approach to treat supraventricular arrhythmias. Atrial fibrillation (AF) 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 (RFA) or cryoablation, is being studied in the treatment of various types of atrial fibrillation.

Atrial fibrillation (AF) 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 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 can be subdivided into three types: 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), and permanent. Atrial fibrillation accounts for approximately one third of hospitalization for cardiac rhythm 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 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 electroschock 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.

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

Rhythm control not considered curative. A variety of ablative procedures have been investigated as potentially curative approaches, or as modifiers of 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
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other cardiac surgeries (e.g., valve repair) is an ablative treatment 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.

Catheter Ablation for AF

Radiofrequency ablation using a percutaneous catheter-based approach is widely used to treat 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. 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 strategies that have emerged for focal ablation within the pulmonary veins originally involved segmental ostial ablation guided by pulmonary vein potential (electrical approach) but currently more typically involve circumferential pulmonary vein ablation (anatomic approach). Circumferential pulmonary vein ablation using radiofrequency energy is the most common approach at present.

Use of currently available radiofrequency catheters for atrial fibrillation has a steep learning curve because they require extensive guiding to multiple ablation points. The procedure also can be done using cryoablation technology. One of the potential advantages to cryoablation techniques is that cryoablation catheters have a circular or shaped endpoint, allowing a “one-shot” ablation.

Repeat procedures following an initial radiofrequency ablation are commonly performed if atrial fibrillation recurs or if atrial flutter develops postprocedure. The need for repeat procedures may, in part, depend on clinical characteristics of the patients age, persistent vs. paroxysmal atrial fibrillation, atrial dilatation, and the type of initial ablation performed. Repeat procedures are generally more limited than the initial procedure. Additional clinical factors have been associated with the need for a second procedure, include the length of atrial fibrillation, permanent atrial fibrillation, left-atrial size and left-ventricular ejection fraction.

Regulatory Status
In February 2009, the NaviStar® ThermalCool® Irrigated Deflectable Diagnostic/Ablation Catheter and EZ Steer ThermoCool NAV Catheter (Biosense Webster) received expanded approval by the U.S. Food and Drug Administration (FDA) through the pre-market approval (PMA) process for radiofrequency ablation for treatment of drug-refractory recurrent symptomatic paroxysmal atrial fibrillation.

Devices using laser or cryoablation techniques for substrate ablation have been approved by the FDA through the PMA process for atrial fibrillation. These devices include:

- Arctic Front™ Cardiac CryoAblation Catheter and CryoConsole (Medtronic), in 2010.
- TactiCath™ Quartz Catheter and TactiSysQuartz® Equipment (St. Jude Medical MN) in 2014.
- HeartLight® Endoscopic Ablation System (Cardiofocus) in 2016.
- The Freezor™ Xtra Catheter (Medtronic) in September 2016.

In addition, has also granted approval to numerous catheter ablation systems have been approved by the FDA 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
Catheter Ablation as a Treatment for Atrial Fibrillation

***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 atrioventricular nodal ablation and pacemaker insertion.

Transcatheter radiofrequency ablation or cryoablation to treat atrial fibrillation may be considered medically necessary as an initial treatment for patients with recurrent symptomatic paroxysmal atrial fibrillation (>1 episode, with 4 or fewer episodes in the previous 6 months) 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 radiofrequency ablation or cryoablation to treat atrial fibrillation is considered investigational for all other indications not listed above.

Policy Guidelines

Transcatheter treatment of atrial fibrillation (AF) may include pulmonary vein isolation and/or focal ablation.

There is no single procedure for catheter ablation. 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 electroanatomic 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 long-standing 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.
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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.

The evidence for individuals who have symptomatic paroxysmal or persistent atrial fibrillation who have failed antiarrhythmic medications who receive RFA or cryoablation, includes multiple RCTs and systematic reviews. Relevant outcomes are overall survival, symptoms, morbid events, and quality of life. RCTs comparing RFA with antiarrhythmic medications report that freedom from AF is more likely after ablation than after medications. Results of long-term follow-up of 5 to 6 years after 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. Multiple RCTs comparing cryoablation and RFA have found that cryoablation is noninferior to RFA for AF control. RFA and cryoablation differ in adverse event profiles; for example, cryoablation is associated with higher rates of phrenic nerve paralysis, but may allow a shorter procedure time. Given currently available data, it would be reasonable to consider both RFA and cryoablation effective for catheter ablation of AF foci or pulmonary vein isolation, provided that there is a discussion about the risks and benefits of each. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

Evidence for individuals who have symptomatic AF and congestive heart failure who have failed rate control and antiarrhythmic medications who receive RFA or cryoablation, includes a TEC Assessment, supported by RCTs. Relevant outcomes are overall survival, symptoms, morbid events, and quality of life. Based on 1 available multicenter RCT, the TEC Assessment found that the evidence was sufficient to conclude that catheter ablation improves outcomes more than the alternative, atrioventricular (AV) nodal ablation and pacemaker insertion. Findings from this RCT have been supported by other comparative studies, which have reported improvements in AF. It is reasonable to consider both RFA and cryoablation effective for catheter ablation of AF foci or pulmonary vein isolation, provided that there is a discussion about the risks and benefits of each. The evidence is sufficient to determine qualitatively that the technology results in a meaningful improvement in the net health outcome.

Evidence for individuals who have recurrent symptomatic paroxysmal AF who receive RFA or cryoablation as an initial rhythm-control strategy, includes RCTs, nonrandomized studies, and systematic reviews. Relevant outcomes are overall survival, symptoms, morbid events, and quality of life. The most current RCT with adequate follow-up compared pulmonary vein isolation by catheter ablation (using either cryoablation or RFA) to medical therapy. Catheter ablation was not superior to medical therapy for major cardiovascular outcomes but secondary outcomes including AF recurrence favored catheter ablation. Two other RCTs with low risk of bias compared catheter ablation for pulmonary vein isolation to antiarrhythmic medications. One RCT demonstrated reduced rates of AF recurrence, while the other reported reduced cumulative overall AF burden. Together, these results suggest that, when a rhythm-control strategy is desired, catheter ablation is a reasonable alternative to antiarrhythmic drug therapy. While the RCTs comparing ablation to medical therapy were conducted using RFA, it is reasonable to consider both RFA and cryoablation effective for catheter ablation of AF foci or pulmonary vein isolation, provided that there is a discussion about the risks and benefits of each. The evidence is sufficient to determine qualitatively that the technology results in a meaningful improvement in the net health outcome.

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.
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Applicable codes: 93653, 93654, 93655

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


Specialty Matched Consultant Advisory Panel review 6/2013

Medical Director review 6/2013


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


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


Catheter Ablation as a Treatment for Atrial Fibrillation


Medical Director review 5/2016


Medical Director review 6/2016


Specialty Matched Consultant Advisory Panel review 6/2017

Medical Director review 6/2017


Specialty Matched Consultant Advisory Panel review 6/2018

Medical Director review 6/2018

Specialty Matched Consultant Advisory Panel review 6/2019

Medical Director review 6/2019


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..."
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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)


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 atrioventricular 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)
Catheter Ablation as a Treatment for Atrial Fibrillation

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)


10/1/19  Description section, policy guidelines, and references updated. No change to policy intent. 7/2019 (jd)

12/31/19  The following codes were removed from the Billing/Coding section effective 10/1/2019: 93656, 93657. (jd)

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.