



BlueCross BlueShield
of Alabama

Name of Blue Advantage Policy:

Transcatheter Ablation as a Treatment of Atrial Fibrillation

Policy #: 283
Category: Medical

Latest Review Date: July 2020
Policy Grade: A

BACKGROUND:

Blue Advantage medical policy does not conflict with Local Coverage Determinations (LCDs), Local Medical Review Policies (LMRPs) or National Coverage Determinations (NCDs) or with coverage provisions in Medicare manuals, instructions or operational policy letters. In order to be covered by Blue Advantage the service shall be reasonable and necessary under Title XVIII of the Social Security Act, Section 1862(a)(1)(A). The service is considered reasonable and necessary if it is determined that the service is:

1. *Safe and effective;*
2. *Not experimental or investigational*;*
3. *Appropriate, including duration and frequency that is considered appropriate for the service, in terms of whether it is:*
 - *Furnished in accordance with accepted standards of medical practice for the diagnosis or treatment of the patient's condition or to improve the function of a malformed body member;*
 - *Furnished in a setting appropriate to the patient's medical needs and condition;*
 - *Ordered and furnished by qualified personnel;*
 - *One that meets, but does not exceed, the patient's medical need; and*
 - *At least as beneficial as an existing and available medically appropriate alternative.*

Routine costs of qualifying clinical trial services with dates of service on or after September 19, 2000 which meet the requirements of the Clinical Trials NCD are considered reasonable and necessary by Medicare. Providers should bill **Original Medicare for covered services that are related to **clinical trials** that meet Medicare requirements (Refer to Medicare National Coverage Determinations Manual, Chapter 1, Section 310 and Medicare Claims Processing Manual Chapter 32, Sections 69.0-69.11).*

POLICY:

Effective for dates of service on or after July 1, 2015:

Blue Advantage will treat **transcatheter radiofrequency or cryoablation to treat atrial fibrillation** as a **covered benefit** when used as a treatment for either of the following indications, which have failed to respond to adequate trials of antiarrhythmic medications:

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

Blue Advantage will treat **transcatheter radiofrequency ablation or cryoablation to treat atrial fibrillation** as a **covered benefit** when used as an **initial treatment** for patients with **symptomatic paroxysmal atrial fibrillation** 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.

Blue Advantage will treat **repeat radiofrequency ablation or cryoablation** as a **covered benefit** in patients with **recurrence of atrial fibrillation and/or development of atrial flutter following the initial procedure.**

Blue Advantage will treat **transcatheter radiofrequency ablation or cryoablation to treat atrial fibrillation** as a **non-covered benefit** and as **investigational** as a treatment for **all indications including, but not limited to cases of atrial fibrillation that do not meet the criteria outlined above.**

Blue Advantage does not approve or deny procedures, services, testing, or equipment for our members. Our decisions concern coverage only. The decision of whether or not to have a certain test, treatment or procedure is one made between the physician and his/her patient. Blue Advantage administers benefits based on the members' contract and medical policies. Physicians should always exercise their best medical judgment in providing the care they feel is most appropriate for their patients. Needed care should not be delayed or refused because of a coverage determination.

DESCRIPTION OF PROCEDURE OR SERVICE:

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 radiofrequency ablation (RFA) or cryoablation, is being studied as a treatment option for various types of AF.

Atrial Fibrillation

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

AF accounts for approximately one-third of hospitalizations for cardiac rhythm disturbances. Symptoms of AF (e.g., palpitations, decreased exercise tolerance, 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 AF are at higher risk for stroke, with anticoagulation is typically recommended. AF is also associated with other cardiac conditions, such as valvular heart disease, heart failure, hypertension, and diabetes. Although episodes of AF can be converted to normal sinus rhythm using pharmacologic or electroshock conversion, the natural history of AF is that of recurrence, thought to be related to fibrillation-induced anatomic and electrical remodeling of the atria.

AF 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), 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 management of AF, 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 with rate control.

However, rhythm control is not 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 AF 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 (e.g., valve repair), is an ablative treatment that involves sequential atriotomy incisions designed to create electrical barriers that prevent the maintenance of AF.

Catheter Ablation for Atrial Fibrillation

Radiofrequency ablation (RFA) 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 AF, because there may be no single arrhythmogenic focus. AF most 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, percutaneous ablation techniques. 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. Research into specific ablation and pulmonary vein isolation techniques is ongoing.

Use of current radiofrequency catheters for AF 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 of cryoablation is that cryoablation catheters have a circular or shaped end point, permitting a “one-shot” ablation.

Repeat Procedures

Repeat procedures following initial RFA are commonly performed if AF recurs or if atrial flutter develops postprocedure. The need for repeat procedures may, in part, depend on the clinical characteristics of the patient (e.g., age, persistent vs paroxysmal AF, atrial dilatation), and the type of ablation initially performed. Repeat procedures are generally more limited in scope than the initial procedure. Additional clinical factors are associated with the need for a second procedure, including age, length of AF, permanent AF, left atrial size, and left ventricular ejection fraction.

KEY POINTS:

The most recent literature search was performed through March 19, 2020.

Summary of Evidence

For individuals who have symptomatic paroxysmal or persistent AF who have failed antiarrhythmic drugs who receive RFA or cryoablation, the evidence includes multiple RCTs and systematic reviews. Relevant outcomes are overall survival, symptoms, morbid events, and quality of life. RCTs comparing RFA with antiarrhythmic medications have reported that freedom from AF is more likely after ablation than after medications. Results of long-term follow-up (5-6 years) after ablation have demonstrated that late recurrences continue in patients who are free of AF at 1 year. However, most patients who are AF-free at 1 year remain AF-free at 5 to 6 years. Multiple RCTs comparing cryoablation with RFA have found that cryoablation is noninferior to RFA for AF control. RFA and cryoablation differ in their adverse event profiles. For example, cryoablation is associated with higher rates of phrenic nerve paralysis but may permit a shorter procedure time. Given current data, it would be reasonable to consider both RFA and cryoablation effective for catheter ablation of AF foci or pulmonary vein isolation, provided 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.

For individuals who have symptomatic AF and congestive heart failure who have failed rate control and antiarrhythmic drugs who receive RFA or cryoablation, the evidence includes RCTs and systematic reviews. Relevant outcomes are overall survival, symptoms, morbid events, and quality of life. Findings from RCTs 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 that the technology results in a meaningful improvement in the net health outcome.

For individuals who have recurrent symptomatic paroxysmal AF who receive RFA or cryoablation as an initial rhythm-control strategy, the evidence 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. QOL measures reported in this RCT favored catheter ablation. Two other RCTs with low risk of bias compared catheter ablation for pulmonary vein isolation with 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 with 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 that the technology results in a meaningful improvement in the net health outcome.

Practice Guidelines and Position Statements

Heart Rhythm Society et al

An expert consensus document on catheter and surgical catheter ablation for atrial fibrillation (AF) was developed jointly by 7 cardiac specialty societies (Heart Rhythm Society [HRS], European Heart Rhythm Association, European Cardiac Arrhythmia Society, American College of Cardiology, American Heart Association, Asia Pacific Heart Rhythm Society, Society of Thoracic Surgeons) in 2012. A related group of cardiac specialty societies (HRS, European Heart Rhythm Association, European Cardiac Arrhythmia Society, Asia Pacific Heart Rhythm Society, Latin American Society of Cardiac Stimulation and Electrophysiology) updated these guidelines in 2017, suggesting the following recommendations for catheter ablation (see Table 1).

Table 1. Guidelines for Management of Catheter Ablation for AF

Recommendation	COR	LOE
Symptomatic AF refractory or intolerant to at least 1 class 1 or 3 antiarrhythmic medication		
Paroxysmal: Catheter ablation is recommended	I	A
Persistent: Catheter ablation is reasonable	IIa	B-NR
Long-standing persistent: Catheter ablation may be considered	IIb	C-LD
Symptomatic AF prior to initiation of antiarrhythmic drug therapy with a class 1 or 3 antiarrhythmic agent		
Paroxysmal: Catheter ablation is reasonable	IIa	B-R
Persistent: Catheter ablation may be considered	IIa	C-EO
Longstanding Persistent: Catheter ablation may be considered	IIb	C-EO

AF: atrial fibrillation; COR: class of recommendation; LOE: level of evidence.

American College of Cardiology et al

In 2014, American College of Cardiology, American Heart Association, and HRS issued guidelines for management of patients with AF. In 2019, the AHA/ACC/HRS conducted a focused update of areas for which new evidence had emerged since the 2014 publication. Together, the guidelines included the following recommendations for rate control and rhythm control (see Table 2).

Table 2. Guidelines for Rate and Rhythm in Management of AF

Recommendation	COR	LOE
Rate control		
“AV nodal ablation with permanent ventricular pacing is reasonable to control heart rate when pharmacological therapy is inadequate and rhythm control is not achievable.”	I	B
“AV nodal ablation with permanent ventricular pacing should not be performed to improve rate control without prior attempts to achieve rate control with medications.”	III ^a	C
Rhythm control		
“AF catheter ablation is useful for symptomatic paroxysmal AF refractory or intolerant to at least 1 class I or III antiarrhythmic medication when a rhythm-control strategy is desired.”	I	A
“Before consideration of AF catheter ablation, assessment of the procedural risks and outcomes relevant to the individual patient is recommended.”	I	C
“AF catheter ablation is reasonable for some patients with symptomatic persistent AF refractory or intolerant to at least 1 class I or III antiarrhythmic medication.”	IIa	A
“In patients with recurrent symptomatic paroxysmal AF, catheter ablation is a reasonable initial rhythm-control strategy before therapeutic trials of antiarrhythmic drug therapy, after weighing the risks and outcomes of drug and ablation therapy.”	IIa	B
“AF catheter ablation may be considered for symptomatic long-standing (>12 months) persistent AF refractory or intolerant to at least 1 class I or III antiarrhythmic medication when a rhythm-control strategy is desired).”	IIb	B
“AF catheter ablation may be considered before initiation of antiarrhythmic drug therapy with a class I or III antiarrhythmic medication for symptomatic persistent AF when a rhythm-control strategy is desired.”	IIb	C
“AF catheter ablation should not be performed in patients who cannot be treated with anticoagulant therapy during and after the procedure.”	III ^a	C
“AF catheter ablation to restore sinus rhythm should not be performed with the sole intent of obviating the need for anticoagulation.”	III ^a	C
“AF catheter ablation may be reasonable in selected patients with symptomatic AF and HF with reduced left ventricular (LV) ejection fraction (HFrEF) to potentially lower mortality rate and reduce hospitalization for HF”	IIb	B-R

AF: atrial fibrillation; AV: arteriovenous; COR: class of recommendation; LOE: level of evidence.

^a Not recommended

Although the guidelines did not make a specific recommendation on the use of cryoablation, they did state that “Cryoballoon ablation is an alternative to point-by-point radiofrequency ablation to achieve pulmonary vein isolation.”

U.S. Preventive Services Task Force Recommendations

Not applicable

KEY WORDS:

Atrial fibrillation, circumferential pulmonary vein ablation (PVA), pulmonary vein isolation, arrhythmogenic, cryoablation, cryoballoon therapy, cryoballoon intervention, cryoballoon technique, cryoballoon isolation, cryoballoon ablation

APPROVED BY GOVERNING BODIES:

In February 2009, the NaviStar® ThermoCool® 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 premarket approval process for RFA to treat drug-refractory recurrent symptomatic paroxysmal AF. FDA product code: OAD.

Devices using laser or cryoablation techniques for substrate ablation have been approved by FDA through the premarket approval process for AF (FDA product code: OAE). They include:

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

Also, numerous catheter ablation systems have been approved by FDA for other ablation therapy for arrhythmias such as supraventricular tachycardia, atrial flutter, and ventricular tachycardia. FDA product code: LPB.

BENEFIT APPLICATION:

Coverage is subject to member’s specific benefits. Group specific policy will supersede this policy when applicable.

CURRENT CODING:

CPT Codes:

93656	Comprehensive electrophysiologic evaluation including transeptal catheterizations, insertion and repositioning of multiple electrode catheters with induction or attempted induction of an arrhythmia including left or right atrial pacing/recording when necessary, right
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	ventricle pacing/recording when necessary, and HIS bundle recording when necessary with intracardiac catheter ablation of atrial fibrillation by pulmonary vein isolation
93657	; additional linear or focal intracardiac catheter ablation of the left or right atrium for treatment of atrial fibrillation remaining after completion of pulmonary vein isolation
93799	Unlisted cardiovascular service or procedure

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POLICY HISTORY:

Adopted for Blue Advantage, January 2007

Available for comment January 31-March 9, 2007

Medical Policy Group, September 2009

Available for comment September 18-November 2, 2009

Medical Policy Group, October 2012

Available for comment
Medical Policy Group, June 2013
Available for comment May 30 through July 13, 2013
Medical Policy Group March 2014
Available for comment May 5 through June 18, 2014
Medical Policy Group June 2014
Available for comment June 30 through August 13, 2014
Medical Policy Group, July 2015
Available for comment July 7 through August 20, 2015
Medical Policy Group, May 2016
Medical Policy Group, June 2017
Medical Policy Group, June 2018
Medical Policy Group, July 2019
Medical Policy Group, July 2020

This medical policy is not an authorization, certification, explanation of benefits, or a contract. Eligibility and benefits are determined on a case-by-case basis according to the terms of the member's plan in effect as of the date services are rendered. All medical policies are based on (i) research of current medical literature and (ii) review of common medical practices in the treatment and diagnosis of disease as of the date hereof. Physicians and other providers are solely responsible for all aspects of medical care and treatment, including the type, quality, and levels of care and treatment.

This policy is intended to be used for adjudication of claims (including pre-admission certification, pre-determinations, and pre-procedure review) in Blue Cross and Blue Shield's administration of plan contracts.