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<b>Medical Benefit</b>		<b>Effective Date:</b> 10/01/16	<b>Next Review Date:</b> 07/17
<b>Preauthorization</b>	No	<b>Review Dates:</b> 05/09, 03/10, 03/11, 03/12, 03/13, 03/14, 03/15, 07/15, 07/16	

**Preauthorization is not required.**

The following Protocol contains medical necessity criteria that apply for this service. The criteria are also applicable to services provided in the local Medicare Advantage operating area for those members, unless separate Medicare Advantage criteria are indicated. If the criteria are not met, reimbursement will be denied and the patient cannot be billed. 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.

Populations	Interventions	Comparators	Outcomes
Individuals: <ul style="list-style-type: none"> <li>With symptomatic paroxysmal or persistent atrial fibrillation who have failed antiarrhythmic drugs</li> </ul>	Interventions of interest are: <ul style="list-style-type: none"> <li>Radiofrequency ablation</li> <li>Cryoablation</li> </ul>	Comparators of interest are: <ul style="list-style-type: none"> <li>Medication management</li> </ul>	Relevant outcomes include: <ul style="list-style-type: none"> <li>Overall survival</li> <li>Symptoms</li> <li>Morbid events</li> <li>Quality of life</li> </ul>
Individuals: <ul style="list-style-type: none"> <li>With symptomatic atrial fibrillation and congestive heart failure who have failed rate control and antiarrhythmic drugs</li> </ul>	Interventions of interest are: <ul style="list-style-type: none"> <li>Radiofrequency ablation</li> <li>Cryoablation</li> </ul>	Comparators of interest are: <ul style="list-style-type: none"> <li>Atrioventricular nodal ablation and pacemaker insertion</li> </ul>	Relevant outcomes include: <ul style="list-style-type: none"> <li>Overall survival</li> <li>Symptoms</li> <li>Morbid events</li> <li>Quality of life</li> </ul>
Individuals: <ul style="list-style-type: none"> <li>With recurrent symptomatic paroxysmal atrial fibrillation</li> </ul>	Interventions of interest are: <ul style="list-style-type: none"> <li>Radiofrequency ablation as an initial rhythm-control strategy</li> <li>Cryoablation as an initial rhythm-control strategy</li> </ul>	Comparators of interest are: <ul style="list-style-type: none"> <li>Medication management</li> </ul>	Relevant outcomes include: <ul style="list-style-type: none"> <li>Overall survival</li> <li>Symptoms</li> <li>Morbid events</li> <li>Quality of life</li> </ul>

### Description

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 RFA or cryoablation, is being studied in the treatment of various types of AF.

### Summary of Evidence

For individuals who have symptomatic paroxysmal or persistent atrial fibrillation (AF) who have failed anti-arrhythmic drugs who receive radiofrequency ablation (RFA) or cryoablation, the evidence includes multiple randomized controlled trials (RCTs) and systematic reviews. Relevant outcomes are overall survival, symptoms,

morbid events, and quality of life. RCTs that compare RFA with antiarrhythmic medications have reported that freedom from AF is more likely after ablation than after medications. Results of long-term follow-up (five to six years) after ablation has demonstrated that late recurrences continue to occur in patients who are free of AF at one year. However, most patients who are AF-free at one year remain AF-free at five to six years. Multiple RCTs comparing cryoablation and RFA have found that cryoablation is noninferior to RFA for AF control. RFA and cryoablation differ in adverse effect 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 qualitatively 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 a TEC Assessment, supported by RCTs. Relevant outcomes are overall survival, symptoms, morbid events, and quality of life. Based on one 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.

For individuals who have recurrent symptomatic paroxysmal AF who receive RFA or cryoablation as an initial rhythm-control strategy, the evidence includes RCTs and systematic reviews. Relevant outcomes are overall survival, symptoms, morbid events, and quality of life. Two 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.

## Policy

Transcatheter radiofrequency ablation or cryoablation to treat atrial fibrillation 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.

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 (more than one episode, with four or fewer episodes in the previous six months) in whom a rhythm-control strategy is desired.

Repeat radiofrequency ablation or cryoablation 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 radiofrequency ablation or cryoablation to treat atrial fibrillation is considered **investigational** as a treatment for cases of atrial fibrillation that do not meet the criteria outlined above.

### Policy Guidelines

Transcatheter treatment of AF may include pulmonary vein isolation and/or focal ablation.

There is no single procedure for catheter ablation, but several variations. Electrical isolation of the pulmonary vein musculature (pulmonary vein isolation) is the cornerstone of most AF 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 AF may need more extensive ablation. Similarly, repeat ablation procedures for recurrent AF 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 three separate procedures, although these repeat procedures may be more limited than the initial procedure.

### Background

#### *Overview of 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 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, and 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 one 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 less 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.

#### *Atrial Fibrillation Treatment Strategies*

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 main-

tain 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.

Currently, the main indications for a rhythm control are for patients with paroxysmal or persistent AF who have hemodynamic compromise associated with episodes of AF 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 AF are typical, and patients with persistent AF may require multiple episodes of cardioversion. Implantable atrial defibrillators, which are designed to detect and terminate an episode of AF, are an alternative in patients otherwise requiring serial cardioversions, but they have not yet achieved widespread use. Patients with paroxysmal AF, by definition, do not require cardioversion but may be treated pharmacologically to prevent further arrhythmic episodes.

Treatment of permanent AF 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 AF.

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 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. 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 (e.g., valve repair, coronary artery bypass grafting).

#### *Catheter Ablation for Atrial Fibrillation*

Radiofrequency ablation (RFA) 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 (see the Catheter Ablation for Cardiac Arrhythmias Protocol). The situation is more complex for AF, because there is no 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 AF. In the late 1990s, it was recognized that AF 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).

The individual lesion set (in addition to the pulmonary vein isolation) and the degree to which the pulmonary vein antrum is electrically isolated vary. Research into specific ablation/pulmonary vein isolation techniques is ongoing. Evidence from a randomized controlled trial (RCT) comparing pulmonary vein isolation alone to pulmonary vein isolation plus ablation to treat patients with electrograms showing complex fractionated activity, and to pulmonary vein isolation plus additional linear ablation across the left atrial roof and mitral valve isthmus, suggests that the more extensive lesion sets do not reduce the AF recurrence rate.<sup>1</sup> Meta-analyses have found that the addition of complex fractionated atrial electrogram ablation to pulmonary vein isolation alone did not improve rates of freedom from recurrent AF,<sup>2-5</sup> although at least one RCT has reported that patients with

ablation of dormant conduction sources outside the pulmonary veins had fewer arrhythmia recurrences than those treated with pulmonary vein isolation alone.<sup>6</sup>

Circumferential pulmonary vein ablation using radiofrequency energy is the most common approach at the present time. The procedure also can be done using cryoablation technology. Use of currently available radiofrequency catheters for AF 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 end point, allowing a “one-shot” ablation. Other types of radiofrequency catheters, such as Medtronic’s radiofrequency-based Pulmonary Vein Ablation Catheter®, which incorporate circular or otherwise shaped end points, may also be used.

Repeat procedures following initial RFA are commonly performed if AF recurs or if atrial flutter develops post-procedure. The need for repeat procedures may, in part, depend on clinical characteristics of the patient (e.g., age, persistent vs. paroxysmal AF, atrial dilatation), 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 when atrial flutter develops after ablation, a “flutter ablation” is performed, which is more limited than the original AF procedure. A number of clinical and demographic factors have been associated with the need for a second procedure, including age, length of AF, permanent AF, 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, South Diamond Bar, CA) received expanded approval by the U.S. Food and Drug Administration (FDA) through the premarket approval (PMA) process for radiofrequency ablation for treatment of drug-refractory recurrent symptomatic paroxysmal atrial fibrillation. FDA product code: OAD.

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

- Arctic Front™ Cardiac CryoAblation Catheter and CryoConsole (Medtronic, Minneapolis, MN) in December 2010.
- TactiCath™ Quartz Catheter and TactiSysQuartz® Equipment (St. Jude Medical, St. Paul, MN) in October 2014.
- HeartLight® Endoscopic Ablation System (Cardiofocus, Marlborough, MA) in April 2016.

In addition, 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.

### Related Protocols

Catheter Ablation for Cardiac Arrhythmias

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

Percutaneous Left Atrial Appendage Closure Devices for Stroke Prevention in Atrial Fibrillation

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.**

## References

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

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