Protocol

Catheter Ablation as Treatment for Atrial Fibrillation

Medical Benefit

Medical Benefit: 10/01/16

Preauthorization

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.

RELATED PROTOCOL

None

<table>
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<th>Populations</th>
<th>Interventions</th>
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<tr>
<td>Individuals: • With symptomatic paroxysmal or persistent atrial fibrillation who have failed antiarrhythmic drugs</td>
<td>Interventions of interest are: • Radiofrequency ablation or cryoablation</td>
<td>Comparators of interest are: • Medication management</td>
<td>Relevant outcomes include: • Overall survival • Symptoms • Morbid events • Quality of life</td>
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<tr>
<td>Individuals: • With symptomatic atrial fibrillation and congestive heart failure who have failed rate control and antiarrhythmic drugs</td>
<td>Interventions of interest are: • Radiofrequency ablation or cryoablation</td>
<td>Comparators of interest are: • Atrioventricular nodal ablation and pacemaker insertion</td>
<td>Relevant outcomes include: • Overall survival • Symptoms • Morbid events • Quality of life</td>
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<tr>
<td>Individuals: • With recurrent symptomatic paroxysmal atrial fibrillation</td>
<td>Interventions of interest are: • Radiofrequency or cryoablation as an initial rhythm-control strategy</td>
<td>Comparators of interest are: • Medication management</td>
<td>Relevant outcomes include: • Overall survival • Symptoms • Morbid events • Quality of life</td>
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DESCRIPTION

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.
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 randomized controlled trials (RCTs) and systematic reviews. Relevant outcomes are overall survival (OS), symptoms, morbid events, and quality of life. The 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 to 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 4 to 6 years. Radiofrequency ablation 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 an 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 OS, symptoms, morbid events, and quality of life. Findings from the 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 an 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 OS, symptoms, morbid events, and quality of life. One 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. Quality of life measures reported in this RCT favored catheter ablation. Two other RCTs with a low risk of bias compared RFA for pulmonary vein isolation with antiarrhythmic medications. One RCT demonstrated reduced rates of AF recurrence, while the other reported reduced cumulative overall AF burden. Additionally, 3 RCTs comparing cryoablation to antiarrhythmic drug therapy as first-line therapy demonstrated improved outcomes for atrial arrhythmia recurrence up to 1 year. In a meta-analysis of 6 RCTs, catheter ablation as first-line therapy significantly reduced the risk of recurrence of atrial arrhythmia and the rate of hospitalizations compared to antiarrhythmic drug therapy. In another meta-analysis of the same RCTs, treatment ranking based on the surface under the cumulative ranking curve put RFA as most likely to be the best treatment for reducing the overall rates of AF recurrence, symptomatic recurrence, and hospitalizations, whereas cryoablation was most likely to reduce serious adverse events. Together, these results suggest that, when a rhythm-control strategy is desired, catheter ablation using RFA or cryoablation is a reasonable alternative to antiarrhythmic drug therapy. The evidence is sufficient to determine that the technology results in an improvement in the net health outcome.

POLICY

Transcatheter radiofrequency ablation (RFA) 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 individuals 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 individuals 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 individuals 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. Electrical isolation of the pulmonary vein musculature (pulmonary vein isolation) is the cornerstone of most AF ablation procedures, but additional ablation sites may 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. Individuals 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 individuals will require a follow-up (repeat) procedure due to recurrence of AF or to development of atrial flutter. In most of the published studies, success rates have been based on having as many as three separate procedures, although these repeat procedures may be more limited in scope than the initial procedure.

BACKGROUND

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 the 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.

Atrial fibrillation can be subdivided into 3 types: paroxysmal, persistent, and permanent. Atrial fibrillation 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 synchrony results in a decreased cardiac output, which can be significant in patients with compromised cardiac function. Also, patients with AF are at higher risk for stroke, with anticoagulation typically recommended. Atrial fibrillation 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.

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 re-establish and maintain normal sinus rhythm. Rhythm control has long been considered an important treatment goal for the 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 so that drug therapy becomes more effective. Ablative approaches focus on the 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 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 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. Atrial fibrillation 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.

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

REPEAT PROCEDURES

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 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 associated with the need for a second procedure include the 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) 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 the 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 the FDA for other ablation therapy for arrhythmias such as supraventricular tachycardia, atrial flutter, and ventricular tachycardia. FDA product code: LPB.

Services that are the subject of a clinical trial do not meet our Technology Assessment and Medically Necessary Services Protocol criteria and are considered investigational. For explanation of experimental and investigational, please refer to the Technology Assessment and Medically Necessary Services 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.


78. Calkins H, Kuck KH, Cappato R, et al. 2012 HRS/EHRA/ECAS expert consensus statement on catheter and surgical ablation of atrial fibrillation: recommendations for patient selection, procedural techniques, patient management and follow-up, definitions, endpoints, and research trial design: a report of the Heart Rhythm Society (HRS) Task Force on Catheter and Surgical Ablation of Atrial Fibrillation. Developed in partnership with the European Heart Rhythm Association (EHRA), a registered branch of the European Society of Cardiology (ESC) and the European Cardiac Arrhythmia Society (ECAS); and in collaboration with the American College of Cardiology (ACC), American Heart Association (AHA), the Asia Pacific Heart Rhythm Society (APHRS), and the Society of Thoracic Surgeons (STS). Endorsed by the governing bodies of the American College of Cardiology Foundation, the American Heart Association, the European Cardiac Arrhythmia Society, the European Heart Rhythm Association, the Society of Thoracic Surgeons, the Asia Pacific Heart Rhythm Society, and the Heart Rhythm Society. Heart Rhythm. Apr 2012;9(4):632-696.e21. PMID 22386883
