Catheter Ablation as Treatment for Atrial Fibrillation

Policy # 00267
Original Effective Date: 09/15/2010
Current Effective Date: 10/09/2019

Applies to all products administered or underwritten by Blue Cross and Blue Shield of Louisiana and its subsidiary, HMO Louisiana, Inc. (collectively referred to as the “Company”), unless otherwise provided in the applicable contract. Medical technology is constantly evolving, and we reserve the right to review and update Medical Policy periodically.

Note: Percutaneous Left-Atrial Appendage Closure Devices for Stroke Prevention in Atrial Fibrillation is addressed separately in medical policy 00296.

When Services May Be Eligible for Coverage
Coverage for eligible medical treatments or procedures, drugs, devices or biological products may be provided only if:

• Benefits are available in the member’s contract/certificate, and
• Medical necessity criteria and guidelines are met.

Based on review of available data, the Company may consider the use of transcatheter radiofrequency ablation (RFA) or cryoablation to treat atrial fibrillation (AF) for certain indications to be eligible for coverage.**

Patient Selection Criteria
The use of transcatheter RFA or cryoablation as a treatment for AF may be eligible for coverage for the following indications which have failed to respond to adequate trials of antiarrhythmic medications:

• Symptomatic paroxysmal or symptomatic persistent AF; or
• As an alternative to atrioventricular (AV) nodal ablation and pacemaker insertion in patients with class II or III congestive heart failure and symptomatic AF.

Based on review of available data, the Company may consider transcatheter RFA or cryoablation to treat AF to be eligible for coverage** as an initial treatment for patients with recurrent symptomatic paroxysmal AF in whom a rhythm-control strategy is desired.

Based on review of available data, the Company may consider repeat RFA or cryoablation in patients with recurrence of AF and/or development of atrial flutter following the initial procedure may be considered eligible for coverage.** (See Policy Guidelines)

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When Services Are Considered Investigational

Coverage is not available for investigational medical treatments or procedures, drugs, devices or biological products.

Based on review of available data, the Company considers the use of transcatheter RFA or cryoablation as a treatment for cases of AF that do not meet the criteria outlined above, to be investigational.*

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 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. 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 AF or to development of atrial flutter. In most published studies, success rates have been based on having as many as 3 separate procedures, although these repeat procedures may be more limited in scope than the initial procedure.

Background/Overview

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
triggers 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 can be subdivided into three types: paroxysmal, persistent, and permanent. AF accounts for approximately one-third of hospitalizations for cardiac rhythm disturbances. Symptoms of AF (eg, 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. 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.

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 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 (eg, 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 (eg, valve repair, coronary artery bypass grafting).
Catheter Ablation as Treatment for Atrial Fibrillation

Policy # 00267
Original Effective Date: 09/15/2010
Current Effective Date: 10/09/2019

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 (see evidence review 2.02.01). 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 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 radiofrequency ablation 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 (eg, 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.

FDA or Other Governmental Regulatory Approval
U.S. Food and Drug Administration (FDA)
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
Catheter Ablation as Treatment for Atrial Fibrillation

Policy # 00267
Original Effective Date: 09/15/2010
Current Effective Date: 10/09/2019

radiofrequency ablation 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.

**Rationale/Source**

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.

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. The relevant outcomes are overall survival, symptoms, morbid events, and quality of life (QOL). 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 one year. However, most patients who are AF-free at one year remain AF-free at five to six years. Multiple RCTs comparing cryoablation with RFA have found that cryoablation is non-inferior 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
Catheter Ablation as Treatment for Atrial Fibrillation

Policy # 00267
Original Effective Date: 09/15/2010
Current Effective Date: 10/09/2019

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. The relevant outcomes are overall survival, symptoms, morbid events, and QOL. 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 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. The relevant outcomes are overall survival, symptoms, morbid events, and QOL. The most current RCT with adequate follow-up compared pulmonary vein isolation by catheter ablation (using either cryoablation or radiofrequency ablation) 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. These 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.

Supplemental Information
Clinical Input From Physician Specialty Societies and Academic Medical Centers
While the various physician specialty societies and academic medical centers may collaborate with and make recommendations during this process, through the provision of appropriate reviewers,
Catheter Ablation as Treatment for Atrial Fibrillation

Policy #  00267
Original Effective Date:  09/15/2010
Current Effective Date:  10/09/2019

Input received does not represent an endorsement or position statement by the physician specialty societies or academic medical centers, unless otherwise noted.

2015 Input
In response to requests, input was received from 3 physician specialty societies (6 reviewers) and 4 academic medical centers while this policy was under review in 2015. Input focused on the use of ablation as an initial procedure for symptomatic paroxysmal and persistent atrial fibrillation (AF) and the use of cryoablation for AF. There was consensus supporting the use of radiofrequency ablation as an initial treatment for symptomatic paroxysmal AF, and the use of cryoablation as an alternative to radiofrequency ablation as a treatment for AF. For the use of radiofrequency ablation as initial treatment for symptomatic persistent AF, support from clinical input was more mixed.

2011 Input
In response to requests, input was received from 2 physician specialty societies (3 reviewers) and 2 academic medical centers while this policy was under review in 2011. While the input was mixed, there was general agreement with the policy statements. One reviewer commented that the use of cryoablation might have a specific role when ablation targets are close to the atrioventricular node.

Practice Guidelines and Position Statements

Heart Rhythm Society et al
An expert consensus document on catheter and surgical catheter ablation for AF was developed jointly by 7 cardiac specialty societies (Heart Rhythm Society, 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 (Heart Rhythm Society, 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).
Catheter Ablation as Treatment for Atrial Fibrillation

Policy # 00267
Original Effective Date: 09/15/2010
Current Effective Date: 10/09/2019

Table 1. Guidelines for Management of Catheter Ablation for AF

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

AF: atrial fibrillation; COR: class of recommendation; LOE: level of evidence.
American College of Cardiology et al

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The American College of Cardiology, American Heart Association, and Heart Rhythm Society (2014) issued guidelines for the management of patients with AF. 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**

<table>
<thead>
<tr>
<th><strong>Recommendation</strong></th>
<th><strong>COR</strong></th>
<th><strong>LOE</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>Rate control</td>
<td></td>
<td></td>
</tr>
<tr>
<td>&quot;AV nodal ablation with permanent ventricular pacing is reasonable to control heart rate when pharmacological therapy is inadequate and rhythm control is not achievable.&quot;</td>
<td>I</td>
<td>B</td>
</tr>
<tr>
<td>&quot;AV nodal ablation with permanent ventricular pacing should not be performed to improve rate control without prior attempts to achieve rate control with medications.&quot;</td>
<td>IIIa</td>
<td>C</td>
</tr>
<tr>
<td>Rhythm control</td>
<td></td>
<td></td>
</tr>
<tr>
<td>&quot;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.&quot;</td>
<td>I</td>
<td>A</td>
</tr>
<tr>
<td>&quot;Before consideration of AF catheter ablation, assessment of the procedural risks and outcomes relevant to the individual patient is recommended.&quot;</td>
<td>I</td>
<td>C</td>
</tr>
<tr>
<td>Recommendation</td>
<td>COR</td>
<td>LOE</td>
</tr>
<tr>
<td>--------------------------------------------------------------------------------</td>
<td>-----</td>
<td>-----</td>
</tr>
<tr>
<td>&quot;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.&quot;</td>
<td>IIA</td>
<td>A</td>
</tr>
<tr>
<td>&quot;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.&quot;</td>
<td>IIA</td>
<td>B</td>
</tr>
<tr>
<td>&quot;AF catheter ablation may be considered for symptomatic long-standing (&gt;12 months) persistent AF refractory or intolerant to at least 1 class I or III antiarrhythmic medication when a rhythm-control strategy is desired.&quot;</td>
<td>IIb</td>
<td>B</td>
</tr>
<tr>
<td>&quot;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.&quot;</td>
<td>IIb</td>
<td>C</td>
</tr>
<tr>
<td>&quot;AF catheter ablation should not be performed in patients who cannot be treated with anticoagulant therapy during and after the procedure.&quot;</td>
<td>IIIa</td>
<td>C</td>
</tr>
<tr>
<td>&quot;AF catheter ablation to restore sinus rhythm should not be performed with the sole intent of obviating the need for anticoagulation.&quot;</td>
<td>IIIa</td>
<td>C</td>
</tr>
</tbody>
</table>
Catheter Ablation as Treatment for Atrial Fibrillation

Policy # 00267
Original Effective Date: 09/15/2010
Current Effective Date: 10/09/2019

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

Medicare National Coverage
There is no national coverage determination. In the absence of a national coverage determination, coverage decisions are left to the discretion of local Medicare carriers.

Ongoing and Unpublished Clinical Trials
Some currently ongoing and unpublished trials that might influence this review are listed in Table 3.

Table 3 Summary of Key Trials

<table>
<thead>
<tr>
<th>NCT No.</th>
<th>Trial Name</th>
<th>Planned Enrollment</th>
<th>Completion Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ongoing</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>NCT02274857a</td>
<td>Randomized Evaluation of Atrial Fibrillation Treatment With Focal Impulse and Rotor Modulation Guided Procedures (REAFFIRM)</td>
<td>350</td>
<td>Nov 2018 (ongoing)</td>
</tr>
</tbody>
</table>
Catheter Ablation as Treatment for Atrial Fibrillation

Policy # 00267  
Original Effective Date: 09/15/2010  
Current Effective Date: 10/09/2019

<table>
<thead>
<tr>
<th>NCT No.</th>
<th>Trial Name</th>
<th>Planned Enrollment</th>
<th>Completion Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>NCT02150902</td>
<td>Augmented Wide Area Circumferential Catheter Ablation for Reduction of Atrial Fibrillation Recurrence (AWARE)</td>
<td>342</td>
<td>Dec 2021</td>
</tr>
<tr>
<td>NCT03365700</td>
<td>Cryoballoon Versus Conventional Radiofrequency Ablation for Persistent Atrial Fibrillation With AF Duration &lt; 2 Years: the IRON-ICE Trial</td>
<td>303</td>
<td>Aug 2020</td>
</tr>
<tr>
<td>NCT01420393</td>
<td>A Randomized Ablation-based Atrial Fibrillation Rhythm Control Versus Rate Control Trial in Patients With Heart Failure and High Burden Atrial Fibrillation</td>
<td>600</td>
<td>Jun 2020</td>
</tr>
<tr>
<td>NCT03295422</td>
<td>Investigator Initiated Randomized Controlled Trial Comparing Two Radiofrequency Ablation Strategies in Patients With Persistent Atrial Fibrillation</td>
<td>200</td>
<td>Dec 2019</td>
</tr>
</tbody>
</table>
Catheter Ablation as Treatment for Atrial Fibrillation

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Original Effective Date:  09/15/2010  
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<table>
<thead>
<tr>
<th>NCT No.</th>
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<th>Planned Enrollment</th>
<th>Completion Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>NCT02106663</td>
<td>Evaluating the Efficacy of Circumferential Pulmonary Vein Ablation (CPVA) Versus Segmental Pulmonary Vein Isolation (SPVI) in Paroxysmal Atrial Fibrillation</td>
<td>100</td>
<td>May 2020</td>
</tr>
<tr>
<td>NCT03387982</td>
<td>Post Procedural Pain Assessment in Patients Undergoing Balloon Cryotherapy Compared to Radiofrequency Ablation (RFA) for Dysplastic Barrett's: A Prospective Study</td>
<td>84</td>
<td>Oct 2022</td>
</tr>
<tr>
<td>Unpublished</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>NCT01687166a</td>
<td>Clinical Evaluation of the Blazer Open-Irrigated Ablation Catheter for the Treatment of Paroxysmal Atrial Fibrillation (ZERO-AF)</td>
<td>298</td>
<td>Oct 2016 (completed)</td>
</tr>
</tbody>
</table>

References

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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 e621. PMID 22386883.


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09/09/2010  Medical Policy Committee review
09/01/2011  Medical Policy Committee review
09/14/2011  Medical Policy Implementation Committee approval. Coverage statements edited for clarity, but no change in intent of coverage statements. Note added at the end of coverage section.
10/11/2012  Medical Policy Committee review
01/23/2013  Coding updated
10/03/2013  Medical Policy Committee review

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10/16/2013 Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
12/04/2014 Medical Policy Committee review
08/03/2015 Coding update: ICD10 Diagnosis code section added; ICD9 Procedure code section removed.
10/08/2015 Medical Policy Committee review
10/21/2015 Medical Policy Implementation Committee approval. Added new policy statement for ablation as initial treatment for paroxysmal atrial fibrillation. Title change.
10/06/2016 Medical Policy Committee review
10/19/2016 Medical Policy Implementation Committee approval. The policy statement for the use of catheter ablation for initial treatment of atrial fibrillation was clarified to state that there should be greater than one episode of atrial fibrillation.
01/01/2017 Coding update: Removing ICD-9 Diagnosis Codes
10/05/2017 Medical Policy Committee review
10/18/2017 Medical Policy Implementation Committee approval. Added a Note, “Transcatheter treatment of atrial fibrillation (AF) may include pulmonary vein isolation and/or focal ablation.” after the coverage section.
10/04/2018 Medical Policy Committee review
10/17/2018 Medical Policy Implementation Committee approval. Coverage eligibility unchanged. Moved the Notes from the coverage section to a Policy Guidelines section.
10/03/2019 Medical Policy Committee review
12/10/2019 Coding update
Next Scheduled Review Date: 10/2020

Coding
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descriptive terms and five character identifying codes and modifiers for reporting medical services and procedures performed by physician.

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Codes used to identify services associated with this policy may include (but may not be limited to) the following:

<table>
<thead>
<tr>
<th>Code Type</th>
<th>Code</th>
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<tbody>
<tr>
<td>CPT</td>
<td>93655, 93656, 93657, 93799</td>
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<tr>
<td>HCPCS</td>
<td>No codes</td>
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<tr>
<td>ICD-10 Diagnosis</td>
<td>148.0-148.91, 150.20-150.23, 150.30-150.33, 150.40-150.43, 150.9</td>
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<tr>
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<td>Codes added eff 1/1/2020: 148.11-148.21</td>
</tr>
</tbody>
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*Investigational – A medical treatment, procedure, drug, device, or biological product is Investigational if the effectiveness has not been clearly tested and it has not been incorporated into standard medical practice. Any determination we make that a medical treatment, procedure, drug, device, or biological product is Investigational will be based on a consideration of the following:

A. Whether the medical treatment, procedure, drug, device, or biological product can be lawfully marketed without approval of the U.S. Food and Drug Administration (FDA) and
Catheter Ablation as Treatment for Atrial Fibrillation

Policy #  00267
Original Effective Date:  09/15/2010
Current Effective Date:  10/09/2019

whether such approval has been granted at the time the medical treatment, procedure, drug, device, or biological product is sought to be furnished; or

B. Whether the medical treatment, procedure, drug, device, or biological product requires further studies or clinical trials to determine its maximum tolerated dose, toxicity, safety, effectiveness, or effectiveness as compared with the standard means of treatment or diagnosis, must improve health outcomes, according to the consensus of opinion among experts as shown by reliable evidence, including:

1. Consultation with the Blue Cross and Blue Shield Association technology assessment program (TEC) or other nonaffiliated technology evaluation center(s);
2. Credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community; or
3. Reference to federal regulations.

**Medically Necessary (or “Medical Necessity”) - Health care services, treatment, procedures, equipment, drugs, devices, items or supplies that a Provider, exercising prudent clinical judgment, would provide to a patient for the purpose of preventing, evaluating, diagnosing or treating an illness, injury, disease or its symptoms, and that are:

A. In accordance with nationally accepted standards of medical practice;
B. Clinically appropriate, in terms of type, frequency, extent, level of care, site and duration, and considered effective for the patient’s illness, injury or disease; and
C. Not primarily for the personal comfort or convenience of the patient, physician or other health care provider, and not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of that patient's illness, injury or disease.

For these purposes, “nationally accepted standards of medical practice” means standards that are based on credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community, Physician Specialty Society recommendations and the views of Physicians practicing in relevant clinical areas and any other relevant factors.

‡ Indicated trademarks are the registered trademarks of their respective owners.

NOTICE: Medical Policies are scientific based opinions, provided solely for coverage and informational purposes. Medical Policies should not be construed to suggest that the Company
Catheter Ablation as Treatment for Atrial Fibrillation

Policy # 00267
Original Effective Date: 09/15/2010
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recommends, advocates, requires, encourages, or discourages any particular treatment, procedure, or service, or any particular course of treatment, procedure, or service.