LOUISIANA BLUE

Catheter Ablation as Treatment for Atrial Fibrillation

Policy # 00267
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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 Are 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 transcatheter radiofrequency ablation (RFA), cryoablation or pulsed field ablation to treat atrial fibrillation (AF) to be **eligible for coverage**** as an initial treatment for individuals with recurrent symptomatic paroxysmal AF (>2 episodes in the previous 6 months) in whom a rhythm-control strategy is desired.

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

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), cryoablation or pulsed field ablation to treat atrial fibrillation (AF) which has failed to respond to an adequate trial of an antiarrhythmic medication to be **eligible for coverage.****

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Patient Selection Criteria

The use of transcatheter RFA, cryoablation or pulsed field ablation to treat AF which has failed to respond to an adequate trial of an antiarrhythmic medication may be eligible for coverage for **EITHER** of the following indications:

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

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 radiofrequency ablation (RFA), cryoablation and pulsed field ablation as a treatment for cases of atrial fibrillation (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 individual to individual, 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 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 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.

It is currently unknown whether there is a feature of the pulsed field ablation approach that alters the conventional 3-month blanking period. Pulsed field ablation is purported to have a desirable safety profile through the avoidance of thermal injury compared to other catheter ablation methods.

Background/Overview

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. These were described in the 2014 American Heart Association/American College of Cardiology/Heart Rhythm Society guidelines on AF management:

- **Paroxysmal (i.e., self-terminating or intermittent) AF** – Paroxysmal AF is defined as AF that terminates spontaneously or with intervention within seven days of onset. Episodes may recur with variable frequency.
- **Persistent AF** – Persistent AF is defined as AF that fails to self-terminate within seven days. Episodes often require pharmacologic or electrical cardioversion to restore sinus rhythm. While a patient who has had persistent AF can have later episodes of paroxysmal AF, AF is generally considered a progressive disease.
- **Long-standing persistent AF** – Long-standing persistent AF refers to AF that has lasted for more than 12 months.
- **Permanent AF** – Permanent AF is a term used to identify persistent AF for which a joint decision by the patient and clinician has been made to no longer pursue a rhythm control strategy. Acceptance of persistent AF may change as symptoms, therapeutic options, and patient and clinician preferences evolve.

While AF typically progresses from paroxysmal to persistent states, patients can present with both types throughout their lives.

Atrial fibrillation 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. 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 (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 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.

Pulsed field ablation (PFA) employs a series of brief electrical pulses to desiccate tissue without significantly heating the tissue and is believed to be more selective for myocardial tissue than other ablative techniques. Two PFA devices were recently approved in the US.

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 (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 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.

Pulsed field ablation (non-thermal energy) devices have also been approved by the FDA for catheter ablation of atrial fibrillation (FDA product code: QZI). FARAPULSE™‡ (Boston Scientific) is approved for paroxysmal AF in drug-resistant patients. PulseSelect™‡ (Medtronic) is approved for both paroxysmal and persistent AF. Sphere-9™‡ Catheter and Affera™‡ Ablation System (Medtronic) is capable of delivering either radiofrequency energy or pulsed field energy is approved for drug refractory, recurrent, symptomatic persistent atrial fibrillation (episode duration less than 1 year).

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

This medical policy was developed through consideration of peer-reviewed medical literature generally recognized by the relevant medical community, U.S. Food and Drug Administration approval status, nationally accepted standards of medical practice and accepted standards of medical practice in this community, technology evaluation centers, reference to regulations, other plan medical policies, and accredited national guidelines.

Description

Atrial fibrillation 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 or cryoablation, is being studied as a treatment option for various types of AF. Pulsed field ablation is a novel ablation technique for atrial fibrillation.

Summary of Evidence

For individuals who have symptomatic paroxysmal or persistent atrial fibrillation (AF) who have failed antiarrhythmic drugs who receive radiofrequency ablation (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. Radio frequency 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 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 ranked 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.

For individuals who have symptomatic paroxysmal or persistent AF who have failed antiarrhythmic drugs who receive pulsed field ablation, the evidence includes RCTs. Relevant outcomes are overall survival (OS), symptoms, morbid events, and quality of life. One noninferiority RCT compared PFA with thermal ablation techniques in patients with paroxysmal AF. PFA was found to be noninferior for the primary composite outcome of initial procedural failure, documented atrial tachyarrhythmia after a 3-month blanking period, antiarrhythmic drug use, cardioversion, or repeat ablation. The incidence of serious adverse events was similar between groups. The publication provided minimal reporting of thermal ablation technique. One noninferiority RCT compared dual energy PFA and RFA to RFA in patients with persistent AF. Dual energy PFA and RFA was found to be noninferior to RFA for the primary effectiveness and safety outcomes. Both RCTs included primarily White participants. Numerous nonrandomized trials have been conducted and found high success rates with acceptable safety. The evidence is insufficient to determine that the technology results in an 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, input received does not represent an endorsement or position statement by the physician specialty societies or academic medical centers, unless otherwise noted.

2025 Input

Clinical input was sought to help determine whether the use of pulsed field ablation for individuals with symptomatic paroxysmal or persistent atrial fibrillation who have failed antiarrhythmic drugs would provide a clinically meaningful improvement in net health outcome and represents generally accepted medical practice in selected patients. In response to requests, clinical input was received from 3 respondents, including 2 specialty society-level responses. For individuals with symptomatic paroxysmal or persistent atrial fibrillation who have failed antiarrhythmic drugs, there was consensus that this use provides a clinically meaningful improvement in net health outcomes and indicates this use is consistent with generally accepted medical practice.

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 (RFA) as an initial treatment for symptomatic paroxysmal AF, and the use of cryoablation as an alternative to RFA as a treatment for AF. For the use of RFA as initial treatment for symptomatic persistent AF, support from clinical input was more mixed.

Practice Guidelines and Position Statements
Guidelines or position statements will be considered for inclusion in 'Supplemental Information' if they were issued by, or jointly by, a US professional society, an international society with US representation, or National Institute for Health and Care Excellence (NICE). Priority will be given to guidelines that are informed by a systematic review, include strength of evidence ratings, and include a description of management of conflict of interest.

Heart Rhythm Society et al
In 2012, 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, and Society of Thoracic Surgeons). [Calkins H, Kuck KH, Cappato R, et al. 2012 HRS/EHR.... 4): 632-696.e21. PMID 22386883] A related group of cardiac specialty societies (Heart Rhythm Society, European Heart Rhythm Association, European Cardiac Arrhythmia Society, Asia Pacific Heart Rhythm Society, and Latin American Society of Cardiac Stimulation and Electrophysiology) updated these guidelines in 2017, [Calkins H, Hindricks G, Cappato R, et al. 2017 HRS.... 20(1): e1-e160. PMID 29016840] suggesting the following recommendations for catheter ablation (see Table 1).

Table 1. Guidelines for Management of Catheter Ablation for Atrial Fibrillation

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, the American College of Cardiology, American Heart Association, American College of Clinical Pharmacy, and Heart Rhythm Society (ACC/AHA/ACCP/HRS) update issued guidelines for the management of patients with AF. The recommendations specific to catheter ablation are summarized in Table 2. In addition, the guidelines recommend, "PVI [pulmonary vein isolation] is recommended as the primary lesion set for all patients unless a different specific trigger is identified." However, no particular ablation method is recommended.

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:

Table 2. Guidelines for Rate and Rhythm in Management of Atrial Fibrillation

Recommendation	COR[a]	LOE[b]
"In patients with symptomatic AF in whom antiarrhythmic drugs have been ineffective, contraindicated, not tolerated or not preferred, and continued rhythm control is desired, catheter ablation is useful to improve symptoms."	1	A
"In selected patients (generally younger with few comorbidities) with symptomatic paroxysmal AF in whom rhythm control is desired, catheter ablation is useful as first-line therapy to improve symptoms and reduce progression to persistent AF."	1	A
"In patients with symptomatic or clinically significant AFL, catheter ablation is useful for improving symptoms."	1	A
"In patients who are undergoing ablation for AF, ablation of additional clinically significant supraventricular arrhythmias can be useful to reduce the likelihood of future arrhythmia."	2a	B-NR
"In patients (other than younger with few comorbidities) with symptomatic paroxysmal or persistent AF who are being managed with a rhythm-control strategy, catheter ablation as first-line therapy can be useful to improve symptoms."	2a	B-R
"In selected patients with asymptomatic or minimally symptomatic AF, catheter ablation may be useful for reducing progression of AF and its associated complications."	2b	B-NR
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

Rate control		
"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 LV ejection fraction (HFrEF) to potentially lower mortality rate and reduce hospitalization for HF."	IIb	B-R

AF: atrial fibrillation; AFL: atrial flutter; AV: atrioventricular; COR: class of recommendation; HF: Heart Failure; HFrEF: heart failure with left ventricular ejection fraction; LOE: level of evidence; LV: left ventricular.
[a] Where 1 is a strong recommendation, 2a is moderate, and 2b is a weak recommendation.
b Where Level A is evidence from more than 1 RCT/meta-analyses of RCTs, Level B-R is moderate quality evidence from 1 ore more RCTs, and Level B-NR is moderate quality evidence from 1 or more well-designed nonrandomized studies.

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 RFA to achieve pulmonary vein isolation."

American Heart Association
In 2021, the American Heart Association published a scientific statement regarding the management of atrial fibrillation in patients with heart failure. The statement included the following:

"In patients with AF and heart failure with reduced ejection fraction (HFrEF) who already have an indication for a cardiac resynchronization therapy defibrillator (CRT-D) device such as left bundle-branch block (LBBB) and in whom AF remains poorly controlled despite maximum efforts at restoration and maintenance of sinus rhythm or pharmacological rate control, atrioventricular node (AVN) ablation should be considered for rate control and promotion of adequate biventricular pacing

- In patients with AF and HFrEF who have a narrow QRS but in whom AF remains poorly controlled despite maximum efforts at restoration and maintenance of sinus rhythm or pharmacological rate control, a strategy of AV node ablation with cardiac resynchronization therapy (CRT) implantation is reasonable, and
- In patients with AF and HFrEF, surgical AF ablation is reasonable in those patients undergoing concomitant cardiac surgery"

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

NCT No.	Trial Name	Planned Enrollment	Completion Date
Ongoing			
NCT05159492	Ground-Breaking Electroporation-based Intervention for PAROXysmal Atrial Fibrillation Treatment (BEAT PAROX-AF)	292 (Actual)	Feb 2025
NCT05971693	Safety and Effectiveness Evaluation of the OMNYPULSE Catheter With the TRUPULSE	160	Apr 2025

NCT No.	Trial Name	Planned Enrollment	Completion Date
	Generator for Treatment of Paroxysmal Atrial Fibrillation (PAF)		
NCT06039722	Prospective, Multicenter, Single-arm Clinical Trial Evaluating the Safety and Efficacy of the Pulse Field Ablation System in Combination With the Pulse Field Ablation Catheter for the Treatment of Paroxysmal Atrial Fibrillation	166	Aug 2024
NCT05717725	Pulsed-field Ablation Versus Sham Ablation to Treat Atrial Fibrillation	60	Dec 2024
NCT04942171	EMOTIon and COgNitive Function After Atrial FibrillationCatheter Ablation vs. Medical Therapy; Randomized Clinical Trial (EMOTICON Trial)	320	Feb 2026
NCT02150902	Augmented Wide Area Circumferential Catheter Ablation for Reduction of Atrial Fibrillation Recurrence (AWARE)	411	Sep 20232025
NCT04037397	First Line Radiofrequency Ablation Versus Antiarrhythmic Drugs for Persistent Atrial Fibrillation Treatment (RAAFT-3)	12025 (Actual)	Mar 2025Oct 2024
NCT05534581	Single Shot Pulmonary Vein Isolation: Comparison of Cryoballoon vs. Pulsed Field Ablation in Patients With Symptomatic Paroxysmal Atrial Fibrillation - A Multi-Center Non-Inferiority Design Clinical Trial (The SINGLE SHOT CHAMPION Trial)	210	Jan 2027
Unpublished			
NCT02106663	Evaluating the Efficacy of Circumferential Pulmonary Vein Ablation (CPVA) Versus Segmental Pulmonary Vein Isolation (SPVI) in Paroxysmal Atrial Fibrillation	97	Dec 2021

NCT: national clinical trial.

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Policy History

Original Effective Date: 09/15/2010
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09/09/2010	Medical Policy Committee review
09/15/2010	Medical Policy Implementation Committee approval. New Policy.
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
10/31/2012	Medical Policy Implementation Committee approval. Rationale section updated. Coverage eligibility unchanged.
01/23/2013	Coding updated
10/03/2013	Medical Policy Committee review
10/16/2013	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
12/04/2014	Medical Policy Committee review
12/17/2014	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
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

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10/09/2019	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
12/10/2019	Coding update
10/01/2020	Medical Policy Committee review
10/07/2020	Medical Policy Implementation Committee approval. Added parameters for atrial fibrillation to the eligible for coverage statement for transcatheter RFA or cryoablation to treat atrial fibrillation as an initial treatment for patients with recurrent symptomatic paroxysmal AF (>1 episode, with ≤4 episodes in the previous 6 months) in whom a rhythm-control strategy is desired. Added a *Note* regarding arrhythmias to the Policy Guidelines section.
10/07/2021	Medical Policy Committee review
10/13/2021	Medical Policy Implementation Committee approval Coverage eligibility unchanged.
10/06/2022	Medical Policy Committee review
10/11/2022	Medical Policy Implementation Committee approval. Replaced "patients" with "individuals" in the coverage section. Coverage eligibility unchanged.
04/06/2023	Medical Policy Committee review
04/12/2023	Medical Policy Implementation Committee approval. Replaced "patients" with "individuals". Patient Selection Criteria statement requires only one adequate trial of an antiarrhythmic medication to have failed instead of "trials" and "medications". Added a reference to see the Policy Guidelines which includes the classification of patients with atrial fibrillation.
04/04/2024	Medical Policy Committee review
04/10/2024	Medical Policy Implementation Committee approval. Changed eligible for coverage statement for transcatheter radiofrequency ablation or cryoablation as an initial treatment of recurrent symptomatic paroxysmal atrial fibrillation from ≤4 episodes to ≥2 episodes.
04/03/2025	Medical Policy Committee review
04/09/2025	Medical Policy Implementation Committee approval. Added a When Services Are Eligible For Coverage heading for the coverage statements without separate criteria. Added pulsed field ablation to the eligible for coverage and investigational statements.

Next Scheduled Review Date: 04/2026

Coding

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

Code Type	Code
CPT	93655, 93656, 93657, 93799
HCPCS	No codes
ICD-10 Diagnosis	All Related Diagnoses

*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 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 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.

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NOTICE: Federal and State law, as well as contract language, including definitions and specific contract provisions/exclusions, take precedence over Medical Policy and must be considered first in determining eligibility for coverage.