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

Policy # 00624
Original Effective Date: 11/01/2018
Current Effective Date: 09/11/2023

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: Catheter Ablation as Treatment for Atrial Fibrillation is addressed separately in medical policy 00267.

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 the maze or modified maze procedure, performed on a non–beating heart during cardiopulmonary bypass with concomitant cardiac surgery for treatment of symptomatic atrial fibrillation (AF) or flutter to be **eligible for coverage.****

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 stand-alone minimally invasive, off-pump maze procedures (ie, modified maze procedures), including those done via mini-thoracotomy for treatment of atrial fibrillation (AF) or flutter to be **investigational.***

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Based on review of available data, the Company considers hybrid ablation (defined as a combined percutaneous and thoracoscopic approach) for the treatment of atrial fibrillation (AF) or flutter to be **investigational.***

Based on review of available data, the Company considers the use of an open maze or modified maze procedure performed on a non-beating heart during cardiopulmonary bypass without concomitant cardiac surgery for the treatment of atrial fibrillation or flutter to be **investigational.***

Based on review of available data, the Company considers the maze or modified maze procedures for any indication not listed above to be **investigational.***

Policy Guidelines

Given the availability of less-invasive alternative approaches to treat atrial fibrillation, performing the maze procedure without concomitant cardiac surgery should rarely be needed.

Per the 2017 Expert Consensus Statement by the Heart Rhythm Society, European Heart Rhythm Association, and European Cardiac Arrhythmia Society (Calkins et al, 2017, referenced in the Supplemental Information section), the indication for concomitant open or closed surgical ablation, stand-alone, and hybrid surgical ablation of atrial fibrillation is symptomatic disease refractory or intolerant to at least 1 Class I or III antiarrhythmic medication.

Background/Overview

Atrial Fibrillation

Atrial fibrillation (AF) is a supraventricular tachyarrhythmia characterized by disorganized atrial activation with ineffective atrial ejection. The underlying mechanism of AF involves the interplay between electrical triggering events that initiate AF 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. The atria are frequently abnormal in individuals with AF and demonstrate enlargement or increased conduction time. Atrial flutter is a variant of AF.

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Epidemiology
In the US, more than 3 to 6 million people have AF and it has been estimated that more than 12 million people will have AF by 2030. Age, body mass index, height, hypertension, diabetes mellitus, obstructive sleep apnea, myocardial infarction, heart failure, hyperthyroidism, chronic kidney disease, smoking, moderate to heavy alcohol consumption, and genetic predisposition are all risk factors for AF. Age-adjusted AF incidence and prevalence is higher among men than women, although the lifetime risk is similar at 24% for men and 22% for women. AF incidence and prevalence appear lower in individuals who are Black compared to White, despite a higher burden of comorbidities. However, this difference is likely largely explained by differential detection of AF by race/ethnicity.

Treatment
The first-line treatment for AF usually includes medications to maintain sinus rhythm and/or control the ventricular rate. Antiarrhythmic medications are only partially effective; therefore, medical treatment is not sufficient for many individuals. Percutaneous catheter ablation, using endocardial ablation, is an accepted second-line treatment for individuals who are not adequately controlled on medications and may also be used as first-line treatment. Catheter ablation (CA) is successful in maintaining sinus rhythm for most individuals, but long-term recurrences are common and increase over time. Performed either by open surgical techniques or thoracoscopy, surgical ablation is an alternative approach to percutaneous CA.

FDA or Other Governmental Regulatory Approval

U.S. Food and Drug Administration (FDA)
Several radiofrequency ablation systems have been cleared for marketing by the U.S. Food and Drug Administration through the 510(k) process for cardiac tissue ablation (product code OCL). Table 1 provides a select list.

Table 1. Radiofrequency Ablation Approved by the U.S. Food and Drug Administration

Device	Manufacturer		
EPi-Sense Guided Coagulation System	Atricure		
Medtronic DiamondTemp™‡ System	Medtronic		

Cobra Fusion Ablation System	AtriCure		
Medtronic Cardioblate®‡ and Cardioblate Gemini™‡ Systems	Medtronic		
Cardima Ablation System	Cardima		
Epicor™‡ Medical Ablation System	Epicor Medical		
Isolator™‡ Systems	AtriCure		
Estech COBRA®‡ Cardiac Electrosurgical Unit	Endoscopic Technologies		
Coolrail™‡ Linear Pen	AtriCure		
Numeris®‡ Guided Coagulation System with VisiTrax®‡	nContact Surgical		
EPi-Sense®‡ Guided Coagulation System with VisiTrax®‡	nContact Surgical		

A number of cryoablation systems, which may be used during cardiac ablation procedures, have also been cleared for marketing, including those in Table 2.

Table 2. Cryoablation Systems Approved by the U.S. Food and Drug Administration

Device	**Manufacturer**	
Cryocare®‡ Cardiac Surgery System	Endocare	
SeedNet™‡ System	Galil Medical	
SurgiFrost®‡ XL Surgical CryoAblation System	CryoCath Technologies; now Medtronic	
Isis™‡ cryosurgical unit	Galil Medical	
Artic Front Advance™‡ and Arctic Front Advance Pro™‡ and the Freezor Max™‡ Cardiac Cryoablation Catheters	Medtronic	

Rationale/Source

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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 federal regulations, other plan medical policies, and accredited national guidelines.

There are various surgical approaches to treat atrial fibrillation (AF) that work by interrupting abnormal electrical activity in the atria. Open surgical procedures, such as the Cox maze procedure were first developed for this purpose and are now generally performed in conjunction with valvular or coronary artery bypass graft surgery. Surgical techniques have evolved to include minimally invasive approaches that use epicardial radiofrequency ablation, a thoracoscopic or mediastinal approach, and hybrid catheter ablations/open procedures.

Summary of Evidence
For individuals who have symptomatic AF or flutter who are undergoing cardiac surgery with bypass who received a Cox maze or a modified maze procedure, the evidence includes several randomized controlled trials (RCTs) and nonrandomized comparative studies, along with systematic reviews of these studies. Relevant outcomes are overall survival, medication use, and treatment-related morbidity. Several small RCTs have provided most of the direct evidence confirming the benefit of a modified maze procedure for individuals with AF who are undergoing mitral valve surgery. These trials have established that the addition of a modified maze procedure results in a lower incidence of atrial arrhythmias following surgery, with minimal additional risks. Observational studies have supported these RCT findings. The evidence is sufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have symptomatic, drug-resistant AF or flutter who are not undergoing cardiac surgery with bypass who receive minimally invasive, off-pump thoracoscopic maze procedures, the evidence includes RCTs and observational studies, some of which identify control groups. Relevant outcomes are overall survival, medication use, and treatment-related morbidity. Two RCTs reported significantly higher rates of freedom from AF at 1-year with surgical ablation but also reported significantly higher rates of serious adverse events. The remaining 2 RCTs found no significant differences between treatment groups in rates of freedom from AF and either did not assess or did not find significant differences in serious adverse events. The comparative observational studies

consistently found significantly higher rates of freedom from atrial arrhythmias but lacked assessment of serious adverse events. The noncomparative studies generally only reported short-term outcomes and did not consistently report adverse events. Therefore, this evidence does not permit definitive conclusions about whether a specific approach is superior to the other. Factors, such as previous treatment, the probability of maintaining sinus rhythm, the risk of complications, contraindications to anticoagulation, and patient preference, may all affect the risk-benefit ratio for each procedure. Additionally, the studies do not permit conclusions about harm due to heterogeneous measurement across studies, with mixed results. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have symptomatic, drug-resistant AF or flutter who are not undergoing cardiac surgery with bypass who receive hybrid thoracoscopic and endocardial ablation procedures, the evidence includes 4 RCTs (sample sizes ranging from 41 to 153) , nonrandomized studies that compared a 'convergent' hybrid approach (ie, epicardial approach combined with endocardial ablation) to catheter ablation (CA) , and 1 observational study that compared a thoracoscopic epicardial ablation with a percutaneous trans-septal procedure hybrid approach to CA. Pooled evidence from randomized and nonrandomized studies found an increased rate of AF-free survival and increased risk of periprocedural adverse events with hybrid procedures relative to standard ablation. Adverse events after the periprocedural period have not been reported. Multicenter RCTs are needed that assess both benefits and harms with at least 1-year of follow-up. At least 2 RCTs of hybrid procedures have been completed but not published (see table 8). 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.

2013 Input
In response to requests, input was received from 2 physician specialty societies and 6 academic medical centers (4 reviewers) while this policy was under review in 2013. There was consensus on the medically necessary statements. For subgroups of populations (eg, those who have failed percutaneous catheter ablation), there was mixed support without consensus. There was also mixed support for the use of hybrid ablation.

2010 Input
In response to requests, input was received from 1 physician specialty society and 3 academic medical centers (4 reviewers) while this policy was under review in 2010. There was unanimous support for the policy statement regarding with cardiopulmonary bypass maze procedure. There was mixed support for the policy statement on off-bypass (off-pump) maze procedure; some providing input indicated off-pump procedures might be useful in select individuals (eg, those who cannot tolerate anticoagulation). Several providing input also commented on the limited long-term data for off-pump procedures.

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.

Society of Thoracic Surgeons
In 2017, the Society of Thoracic Surgeons published guidelines on the surgical treatment of atrial fibrillation (AF). Recommendations are provided in Table 3.

Table 3. Guidelines on Surgical Treatment of Atrial Fibrillation

Recommendation	COR	LOE
Surgical ablation for AF is recommended at the time of concomitant mitral operations to restore sinus rhythm.	I	A

Surgical ablation for AF is recommended at the time of concomitant isolated aortic valve replacement, isolated CABG surgery, and aortic valve replacement plus CABG operations to restore sinus rhythm.	I	B
Surgical ablation for symptomatic AF in the absence of structural heart disease that is refractory to class I/III antiarrhythmic drugs or catheter-based therapy of both is reasonable as a primary stand-alone procedure to restore sinus rhythm.	IIa	B

AF: atrial fibrillation; CABG: coronary artery bypass graft; COR: class of recommendation; LOE: level of evidence.

American Heart Association et al

In 2019, the American Heart Association, American College of Cardiologists, and Heart Rhythm Society issued joint guidelines in collaboration with the Society of Thoracic Surgeons on the management of individuals with AF. Recommendations on the use of surgical ablation to maintain sinus rhythm are provided in Table 4.

Table 4. Guidelines on the Management of Atrial Fibrillation

Recommendation	COR	LOE
"AF catheter ablation may be reasonable in selected individuals with symptomatic AF and HF with reduced left ventricular (LV) ejection fraction (HFrEF) to potentially lower mortality rate and reduce hospitalization for HF (S6.3.4-1, S6.3.4-2)."	IIb	B-R

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

Heart Rhythm Society et al

A 2017 expert consensus statement on catheter and surgical ablation of atrial fibrillation was developed by the Heart Rhythm Society, European Heart Rhythm Association, and European Cardiac Arrhythmia Society. The statement was endorsed by 4 other cardiology associations. Recommendations on concomitant surgical ablation in individuals undergoing cardiac surgery for other purposes and who have symptomatic AF are provided in Table 5.

Table 5. Guidelines on Concomitant Surgical Ablation in Individuals Undergoing Cardiac Surgery[a]

Recommendation	COR	LOE
Paroxysmal: Surgical ablation is recommended for individuals undergoing surgery for other indications	II	B-NR
Persistent: Surgical ablation is recommended for individuals undergoing surgery for other indications	II	B-NR
Longstanding Persistent: Surgical ablation is recommended for individuals undergoing surgery for other indications	II	NR

COR: class of recommendation; LOE: level of evidence; NR: nonrandomized.
a: For individuals with symptomatic AF prior to initiation of antiarrhythmic therapy with Class I or III antiarrhythmic medication and an indication for concomitant closed surgical ablation for AF, surgical ablation is reasonable for paroxysmal, persistent, and long-standing persistent disease (Class: IIa; LOE: B-NR).

The following recommendations were made on stand-alone and hybrid surgical ablation in individuals with symptomatic AF refractory or intolerant to at least 1 class 1 or 3 antiarrhythmic medication (Table 6).

Table 6. Guidelines on Stand-Alone and Hybrid Surgical Ablation for Symptomatic Atrial Fibrillation Refractory or Intolerant to Antiarrhythmics

Recommendation[a]	COR	LOE
Paroxysmal		
Stand alone surgical ablation can be considered for individuals who have not failed catheter ablation but prefer a surgical approach	IIb	B-NR
Stand alone surgical ablation can be considered for individuals who have failed 1 or more attempts at catheter ablation	IIb	B-NR
Persistent		

Stand alone surgical ablation is reasonable for individuals who have not failed catheter ablation but prefer a surgical approach	IIa	B-NR
Stand alone surgical ablation is reasonable for individuals who have failed 1 or more attempts at catheter ablation	IIa	B-NR
Longstanding persistent		
Stand alone surgical ablation is reasonable for individuals who have not failed catheter ablation but prefer a surgical approach	IIb	B-NR
Stand alone surgical ablation is reasonable for individuals who have failed 1 or more attempts at catheter ablation	IIb	B-NR

COR: class of recommendation; LOE: level of evidence; NR: nonrandomized. a: The recommendations noted that "it might be reasonable to apply the indication for stand-alone surgical ablation described above to individuals being considered for hybrid surgical AF ablation."

American Association for Thoracic Surgery

In 2017, the American Association for Thoracic Surgery published guidelines on surgical ablation for AF. Recommendations on concomitant surgical ablation in individuals with AF are provided in Table 7.

Table 7. Guidelines on Concomitant Surgical Ablation in Individuals with Atrial Fibrillation

Recommendation	COR	LOE
"Addition of a concomitant surgical ablation procedure for AF does not increase the incidence of perioperative morbidity."	IIa	A, B-R, B-NR[a]
"Addition of a concomitant surgical ablation procedure for AF does not change the incidence of perioperative stroke/TIA."	IIa	A

"Addition of a concomitant surgical ablation procedure for AF does not change the incidence of late stroke/TIA, but subgroup analysis of nonrandomized controlled trials found a significant reduction in late stroke/TIA incidence."	IIa	A, B-NR[b]
"A surgical procedure that includes concomitant surgical ablation for AF does improve HRQL."	IIa	B-R
"Addition of concomitant surgical ablation for AF does improve AF-related symptoms, and this improvement is greater than in individuals without surgical ablation for AF."	IIa	C-LD
"Addition of concomitant surgical ablation for AF does improve 30-day operative mortality."	I	A
"Addition of a concomitant surgical ablation procedure for AF improves long term survival."	IIa	A, B-NR[c]

AF: atrial fibrillation; COR: class of recommendation; HRQL: health-related quality of life; LOE: level of evidence ; NR: nonrandomized; R: randomized; TIA: transient ischemic attack
a: "LOE A for deep sternal wound infection, pneumonia, reoperation for bleeding, and renal failure requiring dialysis; LOE B-R for intensive care unit length of stay and total hospital length of stay; and LOE B-NR for readmission less than 30 days and renal failure."
b: "LOE A for no change in incidence of late stroke/ TIA (up to 1 year of follow-up after surgery) and LOE B-NR for reduction in incidence of late stroke/TIA (>1 year of follow-up after surgery)."
c: "LOE A for no change in long-term survival (up to 1 year after surgery) and LOE B-NR for improvement in long-term survival (>1 year after 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.

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Ongoing and Unpublished Clinical Trials
Some currently ongoing and unpublished trials that might influence this review are listed in Table 8.

Table 8. Summary of Key Trials

NCT No.	Trial Name	Planned Enrollment	Completion Date
Ongoing			
NCT04506814	Comparison of Repeat Endocardial PVI Vs Epicardial Posterior Wall Isolation and LAA Clip Plus PVI for Recurrent Atrial Fibrillation After Prior PVI	162	Dec 2025
NCT03546374	Irrigated Radio Frequency Ablation to Terminate Non-Paroxysmal Atrial Fibrillation (Terminate AF Study)	160	Aug 2024
NCT05723536	LAI-AF Trial: Hybrid Endo-epicardial Partial Left Atrial Isolation vs. Endocardial Ablation in Individuals With Persistent Atrial Fibrillation (PLAI-AF)	80	Dec 2025
NCT03732794	AtriCure CryoICE Lesions for Persistent and Long-standing Persistent Atrial Fibrillation Treatment During Concomitant On-Pump Endo/Epicardial Cardiac Surgery	150	Dec 2026
NCT02393885	Pivotal Study Of A Dual Epicardial & Endocardial Procedure (DEEP) Approach for Treatment of Subjects With Persistent or Long Standing Persistent Atrial Fibrillation With Radiofrequency Ablation	220	Dec 2027

NCT04715425	Thoracoscopic Surgical Versus Catheter Ablation Approaches for Primary Treatment of Persistent Atrial Fibrillation	170	Sep 2028
Unpublished			
NCT02047279	Left Atrium Reduction Versus no Left Atrium Reduction for Individuals With Enlarged Left Atria and Persistent or Long Standing Persistent Atrial Fibrillation Undergoing Mitral Valve Surgery	120	Sep 2017 (completed)
NCT02441738	Hybrid Thoracoscopic Surgical and Transvenous Catheter Ablation Versus Transvenous Catheter Ablation in Persistent and Longstanding Persistent Atrial Fibrillation	41	Dec 2018 (completed)
NCT03737929	Comparison of the Efficacy of Hybrid Ablative Therapy for Individuals With Persistent Atrial Fibrillation Versus Conventional Catheter Ablation	228	Jan 2022 (unknown)
NCT04237389	Comparative Assessment of Catheter and Thoracoscopic Approaches in Individuals With Persistent and Long-standing Persistent Atrial Fibrillation	60	Aug 2022 (unknown)

NCT: national clinical trial.
[a] Denotes industry-sponsored or cosponsored trial.

References

1. Miyasaka Y, Barnes ME, Gersh BJ, et al. Secular trends in incidence of atrial fibrillation in Olmsted County, Minnesota, 1980 to 2000, and implications on the projections for future prevalence. Circulation. Jul 11 2006; 114(2): 119-25. PMID 16818816
2. Colilla S, Crow A, Petkun W, et al. Estimates of current and future incidence and prevalence of atrial fibrillation in the U.S. adult population. Am J Cardiol. Oct 15 2013; 112(8): 1142-7. PMID 23831166

3. Kornej J, Börschel CS, Benjamin EJ, et al. Epidemiology of Atrial Fibrillation in the 21st Century: Novel Methods and New Insights. Circ Res. Jun 19 2020; 127(1): 4-20. PMID 32716709
4. Benjamin EJ, Levy D, Vaziri SM, et al. Independent risk factors for atrial fibrillation in a population-based cohort. The Framingham Heart Study. JAMA. Mar 16 1994; 271(11): 840-4. PMID 8114238
5. Heeringa J, van der Kuip DA, Hofman A, et al. Prevalence, incidence and lifetime risk of atrial fibrillation: the Rotterdam study. Eur Heart J. Apr 2006; 27(8): 949-53. PMID 16527828
6. Heckbert SR, Austin TR, Jensen PN, et al. Differences by Race/Ethnicity in the Prevalence of Clinically Detected and Monitor-Detected Atrial Fibrillation: MESA. Circ Arrhythm Electrophysiol. Jan 2020; 13(1): e007698. PMID 31934795
7. Calkins H, Hindricks G, Cappato R, et al. 2017 HRS/EHRA/ECAS/APHRS/SOLAECE expert consensus statement on catheter and surgical ablation of atrial fibrillation. Europace. Jan 01 2018; 20(1): e1-e160. PMID 29016840
8. Huffman MD, Karmali KN, Berendsen MA, et al. Concomitant atrial fibrillation surgery for people undergoing cardiac surgery. Cochrane Database Syst Rev. Aug 22 2016; 2016(8): CD011814. PMID 27551927
9. Phan K, Xie A, Tian DH, et al. Systematic review and meta-analysis of surgical ablation for atrial fibrillation during mitral valve surgery. Ann Cardiothorac Surg. Jan 2014; 3(1): 3-14. PMID 24516793
10. Reston JT, Shuhaiber JH. Meta-analysis of clinical outcomes of maze-related surgical procedures for medically refractory atrial fibrillation. Eur J Cardiothorac Surg. Nov 2005; 28(5): 724-30. PMID 16143540
11. Gillinov AM, Gelijns AC, Parides MK, et al. Surgical ablation of atrial fibrillation during mitral-valve surgery. N Engl J Med. Apr 09 2015; 372(15): 1399-409. PMID 25853744
12. Budera P, Straka Z, Osmančík P, et al. Comparison of cardiac surgery with left atrial surgical ablation vs. cardiac surgery without atrial ablation in patients with coronary and/or valvular heart disease plus atrial fibrillation: final results of the PRAGUE-12 randomized multicentre study. Eur Heart J. Nov 2012; 33(21): 2644-52. PMID 22930458
13. Van Breugel HN, Nieman FH, Accord RE, et al. A prospective randomized multicenter comparison on health-related quality of life: the value of add-on arrhythmia surgery in patients with paroxysmal, permanent or persistent atrial fibrillation undergoing valvular and/or coronary bypass surgery. J Cardiovasc Electrophysiol. May 2010; 21(5): 511-20. PMID 19925605

14. Saint LL, Damiano RJ, Cuculich PS, et al. Incremental risk of the Cox-maze IV procedure for patients with atrial fibrillation undergoing mitral valve surgery. J Thorac Cardiovasc Surg. Nov 2013; 146(5): 1072-7. PMID 23998785
15. Kim KC, Cho KR, Kim YJ, et al. Long-term results of the Cox-Maze III procedure for persistent atrial fibrillation associated with rheumatic mitral valve disease: 10-year experience. Eur J Cardiothorac Surg. Feb 2007; 31(2): 261-6. PMID 17158057
16. Gerdisch M, Lehr E, Dunnington G, et al. Mid-term outcomes of concomitant Cox-Maze IV: Results from a multicenter prospective registry. J Card Surg. Oct 2022; 37(10): 3006-3013. PMID 35870185
17. Damiano RJ, Badhwar V, Acker MA, et al. The CURE-AF trial: a prospective, multicenter trial of irrigated radiofrequency ablation for the treatment of persistent atrial fibrillation during concomitant cardiac surgery. Heart Rhythm. Jan 2014; 11(1): 39-45. PMID 24184028
18. Gaita F, Ebrille E, Scaglione M, et al. Very long-term results of surgical and transcatheter ablation of long-standing persistent atrial fibrillation. Ann Thorac Surg. Oct 2013; 96(4): 1273-1278. PMID 23915587
19. Watkins AC, Young CA, Ghoreishi M, et al. Prospective assessment of the CryoMaze procedure with continuous outpatient telemetry in 136 patients. Ann Thorac Surg. Apr 2014; 97(4): 1191-8; discussion 1198. PMID 24582049
20. McCarthy PM, Gerdisch M, Philpott J, et al. Three-year outcomes of the postapproval study of the AtriCure Bipolar Radiofrequency Ablation of Permanent Atrial Fibrillation Trial. J Thorac Cardiovasc Surg. Aug 2022; 164(2): 519-527.e4. PMID 33129501
21. van Laar C, Kelder J, van Putte BP. The totally thoracoscopic maze procedure for the treatment of atrial fibrillation. Interact Cardiovasc Thorac Surg. Jan 2017; 24(1): 102-111. PMID 27664426
22. Yi S, Liu X, Wang W, et al. Thoracoscopic surgical ablation or catheter ablation for patients with atrial fibrillation? A systematic review and meta-analysis of randomized controlled trials. Interact Cardiovasc Thorac Surg. Dec 07 2020; 31(6): 763-773. PMID 33166993
23. Phan K, Phan S, Thiagalingam A, et al. Thoracoscopic surgical ablation versus catheter ablation for atrial fibrillation. Eur J Cardiothorac Surg. Apr 2016; 49(4): 1044-51. PMID 26003961
24. Boersma LV, Castella M, van Boven W, et al. Atrial fibrillation catheter ablation versus surgical ablation treatment (FAST): a 2-center randomized clinical trial. Circulation. Jan 03 2012; 125(1): 23-30. PMID 22082673

25. Castellá M, Kotecha D, van Laar C, et al. Thoracoscopic vs. catheter ablation for atrial fibrillation: long-term follow-up of the FAST randomized trial. Europace. May 01 2019; 21(5): 746-753. PMID 30715255
26. Pokushalov E, Romanov A, Elesin D, et al. Catheter versus surgical ablation of atrial fibrillation after a failed initial pulmonary vein isolation procedure: a randomized controlled trial. J Cardiovasc Electrophysiol. Dec 2013; 24(12): 1338-43. PMID 24016147
27. Adiyaman A, Buist TJ, Beukema RJ, et al. Randomized Controlled Trial of Surgical Versus Catheter Ablation for Paroxysmal and Early Persistent Atrial Fibrillation. Circ Arrhythm Electrophysiol. Oct 2018; 11(10): e006182. PMID 30354411
28. Haldar S, Khan HR, Boyalla V, et al. Catheter ablation vs. thoracoscopic surgical ablation in long-standing persistent atrial fibrillation: CASA-AF randomized controlled trial. Eur Heart J. Dec 14 2020; 41(47): 4471-4480. PMID 32860414
29. Kwon HJ, Choi JH, Kim HR, et al. Radiofrequency vs. Cryoballoon vs. Thoracoscopic Surgical Ablation for Atrial Fibrillation: A Single-Center Experience. Medicina (Kaunas). Sep 26 2021; 57(10). PMID 34684060
30. Mahapatra S, LaPar DJ, Kamath S, et al. Initial experience of sequential surgical epicardial-catheter endocardial ablation for persistent and long-standing persistent atrial fibrillation with long-term follow-up. Ann Thorac Surg. Jun 2011; 91(6): 1890-8. PMID 21619988
31. Stulak JM, Dearani JA, Sundt TM, et al. Ablation of atrial fibrillation: comparison of catheter-based techniques and the Cox-Maze III operation. Ann Thorac Surg. Jun 2011; 91(6): 1882-8; discussion 1888-9. PMID 21619987
32. Wang J, Li Y, Shi J, et al. Minimally invasive surgical versus catheter ablation for the long-lasting persistent atrial fibrillation. PLoS One. 2011; 6(7): e22122. PMID 21765943
33. Lawrance CP, Henn MC, Miller JR, et al. A minimally invasive Cox maze IV procedure is as effective as sternotomy while decreasing major morbidity and hospital stay. J Thorac Cardiovasc Surg. Sep 2014; 148(3): 955-61; discussion 962-2. PMID 25048635
34. De Maat GE, Pozzoli A, Scholten MF, et al. Surgical minimally invasive pulmonary vein isolation for lone atrial fibrillation: midterm results of a multicenter study. Innovations (Phila). 2013; 8(6): 410-5. PMID 24356430
35. Massimiano PS, Yanagawa B, Henry L, et al. Minimally invasive fibrillating heart surgery: a safe and effective approach for mitral valve and surgical ablation for atrial fibrillation. Ann Thorac Surg. Aug 2013; 96(2): 520-7. PMID 23773732

36. Cui YQ, Li Y, Gao F, et al. Video-assisted minimally invasive surgery for lone atrial fibrillation: a clinical report of 81 cases. J Thorac Cardiovasc Surg. Feb 2010; 139(2): 326-32. PMID 19660413
37. Edgerton JR, Brinkman WT, Weaver T, et al. Pulmonary vein isolation and autonomic denervation for the management of paroxysmal atrial fibrillation by a minimally invasive surgical approach. J Thorac Cardiovasc Surg. Oct 2010; 140(4): 823-8. PMID 20299028
38. Han FT, Kasirajan V, Kowalski M, et al. Results of a minimally invasive surgical pulmonary vein isolation and ganglionic plexi ablation for atrial fibrillation: single-center experience with 12-month follow-up. Circ Arrhythm Electrophysiol. Aug 2009; 2(4): 370-7. PMID 19808492
39. Pruitt JC, Lazzara RR, Ebra G. Minimally invasive surgical ablation of atrial fibrillation: the thoracoscopic box lesion approach. J Interv Card Electrophysiol. Dec 2007; 20(3): 83-7. PMID 18214660
40. Sirak J, Jones D, Sun B, et al. Toward a definitive, totally thoracoscopic procedure for atrial fibrillation. Ann Thorac Surg. Dec 2008; 86(6): 1960-4. PMID 19022018
41. Speziale G, Bonifazi R, Nasso G, et al. Minimally invasive radiofrequency ablation of lone atrial fibrillation by monolateral right minithoracotomy: operative and early follow-up results. Ann Thorac Surg. Jul 2010; 90(1): 161-7. PMID 20609767
42. Wudel JH, Chaudhuri P, Hiller JJ. Video-assisted epicardial ablation and left atrial appendage exclusion for atrial fibrillation: extended follow-up. Ann Thorac Surg. Jan 2008; 85(1): 34-8. PMID 18154774
43. Yilmaz A, Geuzebroek GS, Van Putte BP, et al. Completely thoracoscopic pulmonary vein isolation with ganglionic plexus ablation and left atrial appendage amputation for treatment of atrial fibrillation. Eur J Cardiothorac Surg. Sep 2010; 38(3): 356-60. PMID 20227287
44. Yilmaz A, Van Putte BP, Van Boven WJ. Completely thoracoscopic bilateral pulmonary vein isolation and left atrial appendage exclusion for atrial fibrillation. J Thorac Cardiovasc Surg. Aug 2008; 136(2): 521-2. PMID 18692667
45. Geuzebroek GS, Bentala M, Molhoek SG, et al. Totally thoracoscopic left atrial Maze: standardized, effective and safe. Interact Cardiovasc Thorac Surg. Mar 2016; 22(3): 259-64. PMID 26705300
46. Vos LM, Bentala M, Geuzebroek GS, et al. Long-term outcome after totally thoracoscopic ablation for atrial fibrillation. J Cardiovasc Electrophysiol. Jan 2020; 31(1): 40-45. PMID 31691391

47. Harlaar N, Oudeman MA, Trines SA, et al. Long-term follow-up of thoracoscopic ablation in long-standing persistent atrial fibrillation. Interact Cardiovasc Thorac Surg. Jun 01 2022; 34(6): 990-998. PMID 34957518
48. Ad N, Henry L, Hunt S, et al. The outcome of the Cox Maze procedure in patients with previous percutaneous catheter ablation to treat atrial fibrillation. Ann Thorac Surg. May 2011; 91(5): 1371-7; discussion 1377. PMID 21457939
49. Castellá M, Pereda D, Mestres CA, et al. Thoracoscopic pulmonary vein isolation in patients with atrial fibrillation and failed percutaneous ablation. J Thorac Cardiovasc Surg. Sep 2010; 140(3): 633-8. PMID 20117799
50. MacGregor RM, Bakir NH, Pedamallu H, et al. Late results after stand-alone surgical ablation for atrial fibrillation. J Thorac Cardiovasc Surg. Nov 2022; 164(5): 1515-1528.e8. PMID 34045056
51. Mhanna M, Beran A, Al-Abdouh A, et al. Hybrid convergent ablation versus endocardial catheter ablation for atrial fibrillation: A systematic review and meta-analysis. J Arrhythm. Dec 2021; 37(6): 1459-1467. PMID 34887950
52. Eranki A, Wilson-Smith AR, Williams ML, et al. Hybrid convergent ablation versus endocardial catheter ablation for atrial fibrillation: a systematic review and meta-analysis of randomised control trials and propensity matched studies. J Cardiothorac Surg. Aug 13 2022; 17(1): 181. PMID 35964093
53. DeLurgio DB, Crossen KJ, Gill J, et al. Hybrid Convergent Procedure for the Treatment of Persistent and Long-Standing Persistent Atrial Fibrillation: Results of CONVERGE Clinical Trial. Circ Arrhythm Electrophysiol. Dec 2020; 13(12): e009288. PMID 33185144
54. Lee KN, Kim DY, Boo KY, et al. Combined epicardial and endocardial approach for redo radiofrequency catheter ablation in patients with persistent atrial fibrillation: a randomized clinical trial. Europace. Oct 13 2022; 24(9): 1412-1419. PMID 35640923
55. van der Heijden CAJ, Weberndörfer V, Vroomen M, et al. Hybrid Ablation Versus Repeated Catheter Ablation in Persistent Atrial Fibrillation: A Randomized Controlled Trial. JACC Clin Electrophysiol. Jan 10 2023. PMID 36752455
56. Jan M, Žižek D, Geršak ŽM, et al. Comparison of treatment outcomes between convergent procedure and catheter ablation for paroxysmal atrial fibrillation evaluated with implantable loop recorder monitoring. J Cardiovasc Electrophysiol. Aug 2018; 29(8): 1073-1080. PMID 29722468

57. DeLurgio DB, Blauth C, Halkos ME, et al. Hybrid epicardial-endocardial ablation for long-standing persistent atrial fibrillation: A subanalysis of the CONVERGE Trial. Heart Rhythm O2. Feb 2023; 4(2): 111-118. PMID 36873309
58. La Meir M, Gelsomino S, Lucà F, et al. Minimally invasive surgical treatment of lone atrial fibrillation: early results of hybrid versus standard minimally invasive approach employing radiofrequency sources. Int J Cardiol. Aug 20 2013; 167(4): 1469-75. PMID 22560495
59. Kress DC, Erickson L, Choudhuri I, et al. Comparative Effectiveness of Hybrid Ablation Versus Endocardial Catheter Ablation Alone in Patients With Persistent Atrial Fibrillation. JACC Clin Electrophysiol. Apr 2017; 3(4): 341-349. PMID 29759446
60. Maclean E, Yap J, Saberwal B, et al. The convergent procedure versus catheter ablation alone in longstanding persistent atrial fibrillation: A single centre, propensity-matched cohort study. Int J Cardiol. Mar 15 2020; 303: 49-53. PMID 32063280
61. Mannakkara NN, Porter B, Child N, et al. Convergent ablation for persistent atrial fibrillation: outcomes from a single-centre real-world experience. Eur J Cardiothorac Surg. Dec 02 2022; 63(1). PMID 36346176
62. Kiankhooy A, Pierce C, Burk S, et al. Hybrid ablation of persistent and long-standing persistent atrial fibrillation with depressed ejection fraction: A single-center observational study. JTCVS Open. Dec 2022; 12: 137-146. PMID 36590727
63. Bisleri G, Rosati F, Bontempi L, et al. Hybrid approach for the treatment of long-standing persistent atrial fibrillation: electrophysiological findings and clinical results. Eur J Cardiothorac Surg. Nov 2013; 44(5): 919-23. PMID 23475587
64. Gehi AK, Mounsey JP, Pursell I, et al. Hybrid epicardial-endocardial ablation using a pericardioscopic technique for the treatment of atrial fibrillation. Heart Rhythm. Jan 2013; 10(1): 22-8. PMID 23064043
65. Gersak B, Pernat A, Robic B, et al. Low rate of atrial fibrillation recurrence verified by implantable loop recorder monitoring following a convergent epicardial and endocardial ablation of atrial fibrillation. J Cardiovasc Electrophysiol. Oct 2012; 23(10): 1059-66. PMID 22587585
66. La Meir M, Gelsomino S, Lorusso R, et al. The hybrid approach for the surgical treatment of lone atrial fibrillation: one-year results employing a monopolar radiofrequency source. J Cardiothorac Surg. Jul 19 2012; 7: 71. PMID 22812613
67. Muneretto C, Bisleri G, Bontempi L, et al. Successful treatment of lone persistent atrial fibrillation by means of a hybrid thoracoscopic-transcatheter approach. Innovations (Phila). 2012; 7(4): 254-8. PMID 23123991

68. Muneretto C, Bisleri G, Bontempi L, et al. Durable staged hybrid ablation with thoracoscopic and percutaneous approach for treatment of long-standing atrial fibrillation: a 30-month assessment with continuous monitoring. J Thorac Cardiovasc Surg. Dec 2012; 144(6): 1460-5; discussion 1465. PMID 23062968
69. Pison L, La Meir M, van Opstal J, et al. Hybrid thoracoscopic surgical and transvenous catheter ablation of atrial fibrillation. J Am Coll Cardiol. Jul 03 2012; 60(1): 54-61. PMID 22742400
70. Zembala M, Filipiak K, Kowalski O, et al. Minimally invasive hybrid ablation procedure for the treatment of persistent atrial fibrillation: one year results. Kardiol Pol. 2012; 70(8): 819-28. PMID 22933215
71. Geršak B, Zembala MO, Müller D, et al. European experience of the convergent atrial fibrillation procedure: multicenter outcomes in consecutive patients. J Thorac Cardiovasc Surg. Apr 2014; 147(4): 1411-6. PMID 23988287
72. Civello KC, Smith CA, Boedefeld W. Combined endocardial and epicardial ablation for symptomatic atrial fibrillation: single center experience in 100+ consecutive patients. J Innovations Cardiac Rhythm Manage. 2013;August.
73. Tonks R, Lantz G, Mahlow J, et al. Short and Intermediate Term Outcomes of the Convergent Procedure: Initial Experience in a Tertiary Referral Center. Ann Thorac Cardiovasc Surg. Feb 20 2020; 26(1): 13-21. PMID 31495813
74. Badhwar V, Rankin JS, Damiano RJ, et al. The Society of Thoracic Surgeons 2017 Clinical Practice Guidelines for the Surgical Treatment of Atrial Fibrillation. Ann Thorac Surg. Jan 2017; 103(1): 329-341. PMID 28007240
75. January CT, Wann LS, Calkins H, et al. 2019 AHA/ACC/HRS Focused Update of the 2014 AHA/ACC/HRS Guideline for the Management of Patients With Atrial Fibrillation: A Report of the American College of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines and the Heart Rhythm Society. J Am Coll Cardiol. Jul 09 2019; 74(1): 104-132. PMID 30703431
76. Ad N, Damiano RJ, Badhwar V, et al. Expert consensus guidelines: Examining surgical ablation for atrial fibrillation. J Thorac Cardiovasc Surg. Jun 2017; 153(6): 1330-1354.e1. PMID 28390766

Policy History

Original Effective Date: 11/01/2018

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

Policy # 00624
Original Effective Date: 11/01/2018
Current Effective Date: 09/11/2023

Current Effective Date: 09/11/2023
08/09/2018 Medical Policy Committee review
08/15/2018 Medical Policy Implementation Committee approval. New policy
08/01/2019 Medical Policy Committee review
08/14/2019 Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
08/06/2020 Medical Policy Committee review
08/12/2020 Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
08/05/2021 Medical Policy Committee review
08/11/2021 Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
08/04/2022 Medical Policy Committee review
08/10/2022 Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
08/03/2023 Medical Policy Committee review
08/09/2023 Medical Policy Implementation Committee approval. Not medically necessary language for the use of an open maze or modified maze procedure performed on a non-beating heart during cardiopulmonary bypass without concomitant cardiac surgery for the treatment of atrial fibrillation or flutter changed to Investigational; intent unchanged.
Next Scheduled Review Date: 08/2024

Coding

The five character codes included in the Blue Cross Blue Shield of Louisiana Medical Policy Coverage Guidelines are obtained from Current Procedural Terminology (CPT®)‡, copyright 2022 by the American Medical Association (AMA). CPT is developed by the AMA as a listing of 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:

Code Type	Code
CPT	33254, 33255, 33256, 33265, 33266 Add codes effective 09/01/2023: 33257, 33258
HCPCS	No codes
ICD-10 Diagnosis	I48.0-I48.92

*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: If the Patient's health insurance contract contains language that differs from the BCBSLA Medical Policy definition noted above, the definition in the health insurance contract will be relied upon for specific coverage determinations.

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