BlueCross BlueShield of Alabama

**Name of Blue Advantage Policy:**

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

Policy #: 631
Latest Review Date: April 2025
Category: Surgery

## BACKGROUND:

***Blue Advantage*** *medical policy does not conflict with Local Coverage Determinations (LCDs), Local Medical Review Policies (LMRPs) or National Coverage Determinations (NCDs) or with coverage provisions in Medicare manuals, instructions or operational policy letters. In order to be covered by Blue Advantage the service shall be reasonable and necessary under Title XVIII of the Social Security Act, Section 1862(a)(1)(A). The service is considered reasonable and necessary if it is determined that the service is:*

1. *Safe and effective;*
2. *Not experimental or investigational*;*
3. *Appropriate, including duration and frequency that is considered appropriate for the service, in terms of whether it is:*
   - *Furnished in accordance with accepted standards of medical practice for the diagnosis or treatment of the patient's condition or to improve the function of a malformed body member;*
   - *Furnished in a setting appropriate to the patient's medical needs and condition;*
   - *Ordered and furnished by qualified personnel;*
   - *One that meets, but does not exceed, the patient's medical need; and*
   - *At least as beneficial as an existing and available medically appropriate alternative.*

**Routine costs of qualifying clinical trial services with dates of service on or after September 19, 2000, which meet the requirements of the Clinical Trials NCD are considered reasonable and necessary by Medicare. Providers should bill* ***Original Medicare*** *for covered services that are related to* ***clinical trials*** *that meet Medicare requirements (Refer to Medicare National Coverage Determinations Manual, Chapter 1, Section 310 and Medicare Claims Processing Manual Chapter 32, Sections 69.0-69.11).*



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## POLICY:

**Blue Advantage** will treat **the maze or modified maze procedure**, performed on a non-beating heart during cardiopulmonary bypass with concomitant cardiac surgery, as a **covered benefit** for symptomatic, atrial fibrillation or atrial flutter. (CPT codes 33257 or 33259)

**Blue Advantage** will treat **stand-alone maze or modified maze procedures** (including open and minimally invasive) as a **covered benefit** in symptomatic patients who (33254, 33255, 33256, 33265, 33266)

- Have failed at least TWO class I or III antiarrhythmic medications and TWO endocardial ablations.

**Blue Advantage** will treat **the hybrid maze procedure** as a **covered benefit** as a stand-alone procedure in symptomatic patients who (CPT code 33999)

- Have failed at least TWO class I or III antiarrhythmic medications and a failed catheter-based therapy.

**Blue Advantage** will treat **stand-alone and hybrid (defined as a combined percutaneous and thoracoscopic approach) maze and modified maze ablation procedures** are considered as a **non-covered benefit** and as **investigational** in all other situations.

*For an alternative approach for the treatment of atrial fibrillation, see medical policy #283 - Transcatheter Ablation of Arrhythmogenic Foci in the Pulmonary Veins as a Treatment of Atrial Fibrillation.*

*Blue Advantage does not approve or deny procedures, services, testing, or equipment for our members. Our decisions concern coverage only. The decision of whether or not to have a certain test, treatment or procedure is one made between the physician and his/her patient. Blue Advantage administers benefits based on the members' contract and medical policies. Physicians should always exercise their best medical judgment in providing the care they feel is most appropriate for their patients. Needed care should not be delayed or refused because of a coverage determination.*

## DESCRIPTION OF PROCEDURE OR SERVICE:

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.

**Atrial Fibrillation**

Atrial fibrillation (AF) is a supraventricular tachyarrhythmia characterized by disorganized atrial activation with ineffective atrial ejection. The underlying mechanism of AF involves 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 patients with AF and demonstrate enlargement or increased conduction time. Atrial flutter is a variant of atrial fibrillation.

**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 patients. Percutaneous catheter ablation, using endocardial ablation, is an accepted second-line treatment for patients who are not adequately controlled on medications and may also be used as first-line treatment. Catheter ablation is successful in maintaining sinus rhythm for most patients, but long-term recurrences are common and increase over time. Surgical ablation, performed either by open surgical techniques or thoracoscopy, is an alternative approach to percutaneous catheter ablation.

**Open Surgical Techniques**

The classic Cox maze III procedure is a complex surgical procedure for patients with AF that involves sequential atriotomy incisions that interrupt the aberrant atrial conduction pathways in the heart. The procedure is also intended to preserve atrial pumping function. It is indicated for patients who do not respond to medical or other surgical antiarrhythmic therapies and is often performed in conjunction with correction of structural cardiac conditions such as valve repair or replacement. This procedure is considered the criterion standard for surgical treatment of drug-resistant AF, with an approximately 90% success rate.

The maze procedure entails making incisions in the heart that:

- direct an impulse from the sinoatrial node to the atrioventricular node;
- preserve activation of the entire atrium; and
- block re-entrant impulses that are responsible for AF or atrial flutter.

The classic Cox maze procedure is performed on a non-beating heart during cardiopulmonary bypass. Simplification of the maze procedure has evolved with the use of different ablation tools such as microwave, cryotherapy, ultrasound, and radiofrequency (RF) energy sources to create the atrial lesions instead of employing the incisional technique used in the classic maze procedure. The Cox maze IV procedure involves the use of RF energy or cryoablation to create transmural lesions analogous to the lesions created by the cut-and-sew maze.

**Minimally Invasive (Thoracoscopic) Techniques**

Less invasive, transthoracic, endoscopic, off-pump procedures to treat drug-resistant AF have been developed. The evolution of these procedures involves both different surgical approaches and different lesion sets. Alternative surgical approaches include mini-thoracotomy and total thoracoscopy with video assistance. Open thoracotomy and mini-thoracotomy employ cardiopulmonary bypass and open heart surgery, while thoracoscopic approaches are performed on the beating heart. Thoracoscopic approaches do not enter the heart and use epicardial ablation lesion sets, whereas the open approaches use either the classic “cut-and-sew” approach or endocardial ablation.

Lesion sets may vary independent of the surgical approach, with a tendency toward less extensive lesion sets targeted to areas that are most likely to be triggers of AF. The most limited lesion sets involve pulmonary vein isolation and exclusion of the left atrial appendage. More extensive lesion sets include linear ablations of the left and/or right atrium and ablation of ganglionic plexi. Some surgeons perform left-atrial reduction in cases of left-atrial enlargement.

The type of energy used for ablation also varies; radiofrequency energy is most commonly applied. Other types of energy sources such as cryoablation and high-intensity ultrasound have also been used. For our purposes, the variations on surgical procedures for AF will be combined under the heading of "modified MAZE" procedures.

**Hybrid Techniques**
"Hybrid" ablation refers to a procedure that uses both thoracoscopic and percutaneous approaches in the same patient. Ablation is performed on the outer surface of the heart (epicardial) via the thoracoscopic approach, and on the inner surface of the heart (endocardial) via the percutaneous approach. The rationale for doing a hybrid procedure is that a combination of both techniques may result in more complete ablation. Thoracoscopic epicardial ablation is limited by the inability to perform all possible ablation lines, because the posterior portions of the heart are not accessible via thoracoscopy. Percutaneous, endoscopic ablation is limited by incomplete ablation lines that often require repeat procedures. By combining both procedures, a full set of ablation lines can be performed, and incomplete ablation lines can be minimized.

The hybrid approach first involves surgical epicardial ablation. Following this procedure, an electrophysiologic study is performed percutaneously followed by endocardial ablation as directed by the results of electrophysiology. The electrophysiology study and endocardial ablation can be done immediately after the thoracoscopy as part of a single procedure, or on separate days, as directed by the electrophysiology study.

## KEY POINTS:
The most recent literature review is through December 11, 2024.

**Summary of Evidence**
For individuals who have symptomatic, atrial fibrillation (AF) or flutter who are undergoing cardiac surgery with bypass who received a Cox maze procedure or 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 patients with AF who are undergoing mitral valve surgery. These trials establish that the addition of a modified MAZE procedure results in a lower incidence of atrial arrhythmias following surgery, with minimal additional risks. Observational studies support the 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 have failed 2 or more endocardial ablations and are not undergoing cardiac surgery with bypass who receive minimally

invasive or stand alone, off-pump maze procedures, the evidence includes RCTs, case series and observational studies, some of which identify control groups. Relevant outcomes are overall survival, medication use, and treatment-related morbidity. Several studies have reported high rates of maintaining sinus rhythm and less need for repeat ablations. Case series with matched control groups have reported higher success rates in maintaining sinus rhythm compared with CA. Some case series and a RCT have included only patients who have failed previous CA. These studies have also reported high success rates following thoracoscopic ablation, suggesting that patients who fail CA may still benefit from thoracoscopic ablation. These studies offer evidence that is more clinically relevant than studies of unselected patients because this population has fewer treatment options and is more likely to benefit from surgical procedures. 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 hybrid thoracoscopic/endocardial ablation procedures, the evidence includes RCTs, nonrandomized studies, single arm case series, systematic reviews, and an observational study. Relevant outcomes are overall survival, medication use, and treatment-related morbidity. Results of the RCTs and nonrandomized comparative studies have generally found an increased rate of AF-free survival and reduced need for cardioversion through 1year with the use of a hybrid procedure as compared to CA in patients with persistent and long-standing AF. Observational studies with mid- and long-term follow-up have estimated freedom from AF following a hybrid procedure at about 2 and 5 years to be approximately 74% and 47%, respectively. The evidence is sufficient to determine that the technology results in an improvement in the net health outcome

**Practice Guidelines and Position Statements**
**Society of Thoracic Surgeons**
In 2023, the Society of Thoracic Surgeons published guidelines for the surgical treatment of atrial fibrillation. Recommendations include the following (see Table 1).

**Table 1: Guidelines on Surgical Treatment of Atrial Fibrillation**

| Recommendation | COR | LOE |
|---|---|---|
| Surgical ablation for AF is recommended for first-time non-emergent concomitant mitral operations to restore sinus rhythm and improve long-term outcomes. | I | A |
| Surgical ablation for AF is recommended for any first-time non-emergent concomitant non-mitral operation to restore sinus rhythm and improve long-term outcomes. | I | B |
| Surgical ablation for symptomatic AF in the absence of structural heart disease that is refractory to class I/III antiarrhythmic drugs, catheter-based therapy or both is reasonable as a primary stand-alone procedure to restore sinus rhythm. | IIa | B |

| | | |
|---|---|---|
| Surgical ablation for symptomatic persistent or longstanding persistent AF in the absence of structural heart disease is reasonable as a stand-alone procedure using the Cox-Maze III/IV lesion set as the preferred procedure. | IIa | B |

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

**American Heart Association, American College of Cardiologists, and Heart Rhythm Society**

The American Heart Association, American College of Cardiologists, American College of Clinical Pharmacy, and Heart Rhythm Society (2023) issued joint guidelines on the diagnosis and management of patients with AF. Recommendations on the use of surgical ablation to maintain sinus rhythm are provided in Table 2.

**Table 2: Guidelines on the Management of Atrial Fibrillation**

| Recommendation | COR | LOE |
|---|---|---|
| For patients with AF who are undergoing cardiac surgery, concomitant surgical ablation can be beneficial to reduce the risk of recurrent AF. | 2a | B |
| For patients with symptomatic, persistent AF refractory to antiarrhythmic drug therapy, a hybrid epicardial and endocardial ablation might be reasonable to reduce the risk of recurrent atrial arrhythmia. | 2b | B |

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

**HRS, European Heart Rhythm Association, and European Cardiac Arrhythmia Society**

A 2024 expert consensus statement was developed regarding catheter and surgical ablation of atrial fibrillation by the HRS, European Heart Rhythm Association, Asia Pacific Heart Rhythm Society, and Latin American Heart Rhythm Society. Recommendations on concomitant surgical ablation in patients undergoing cardiac surgery for other purposes and who have symptomatic AF are provided below. (see Table 3).

**Table 3: Guidelines on Concomitant Surgical Ablation in Patients Undergoing Cardiac Surgery**

| Recommendation | Category of Advice | Type of Evidence |
|---|---|---|
| Concomitant surgical AF ablation is beneficial in patients with paroxysmal or persistent AF undergoing left atrial open cardiac surgery regardless of prior antiarrhythmic drug failure or intolerance | Advice to do | META |
| Concomitant surgical AF ablation is beneficial in patients with | Advice to do | META |

| | | |
|---|---|---|
| paroxysmal or persistent AF intolerant or refractory to previous antiarrhythmic drug therapy, undergoing close (non-left atrial open) cardiac surgery | | |
| Biatrial Cox maze procedure or a minimum of PVI plus left atrial posterior wall isolation is beneficial in patients undergoing surgical AF ablation concomitant to left atrial open cardiac surgery | Advice to do | RAND |
| Concomitant surgical AF ablation is reasonable in patients with paroxysmal or persistent AF prior to initiation of Class I or III antiarrhythmic therapy, undergoing close (non-left atrial open) cardiac surgery | May be appropriate to do | META |

META: Evidence from >1 high-quality RCT or Meta-analyses of high-quality RCTs; RAND: Evidence from 1 high-quality RCT or Evidence from >1 moderate-quality RCT or Meta-analyses of moderate-quality RCTs

The following recommendations were made regarding stand-alone surgical ablation (see Table 4):

Table 4: Guidelines on Stand-Alone and Hybrid Surgical Ablation for Symptomatic AF

| Recommendation | Category of Advice | Type of Evidence |
|---|---|---|
| Stand-alone surgical or hybrid ablation is reasonable in symptomatic patients with persistent AFwith prior unsuccessful catheter ablation and also in those who are intolerant or refractory to antiarrhythmic drug therapy and prefer a surgical/hybrid approach, after careful consideration of relative safety and efficacy of treatment options. | May be appropriate to do | META |
| Stand-alone surgical or hybrid ablation may be reasonable in symptomatic patients with paroxysmal AF with prior unsuccessful catheter ablations who prefer a surgical/hybrid approach, after careful consideration of relative safety and efficacy of treatment options | Area of uncertainty | RAND |

META: Evidence from >1 high-quality RCT or Metaanalyses of high-quality RCTs; RAND: Evidence from 1 high-quality RCT or Evidence from >1 moderate-quality RCT or Metaanalyses of moderate-quality RCTs

**American Association for Thoracic Surgery**

The American Association for Thoracic Surgery (2017) published guidelines on surgical ablation for AF. Recommendations on concomitant surgical ablation in patients with AF are provided in Table 5.

**Table 5. Guidelines on Concomitant Surgical Ablation in Patients with AF**

| 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-NRa |
| "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, IIa C-LD and this improvement is greater than in patients 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 BNR 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.

## KEY WORDS:
Maze procedure, hybrid maze procedure, mini-maze, mini maze, surgical ablation, hybrid, cardiac ablation, atrial fibrillation, minimally invasive technique, thorascopic, hybrid ablation,

mini-thorascopic, modified MAZE, Cardioblate®, Cardima Ablation System, Epicor™, Isolator ™ Transpolar™ Pen,Estech COBRA®, Coolrail™, Numeris®, Epi-Sense®, Cryocare® Cardiac Surgery System, SeedNet™, SurgiFrost® XL , Isis™ cryosurgical unit

## APPROVED BY GOVERNING BODIES:

Several RFA systems used for cardiac tissue ablation have been approved or cleared for marketing by the U.S. Food and Drug Administration through the 510(k) process for cardiac tissue ablation (product code OCL) or PMA process (product code OCM). They include:

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

A number of cryoablation systems which may be used on cardiac ablation procedures have also been cleared for marketing, including:

- The Cryocare® Cardiac Surgery System (Endocare);
- The SeedNet™ System (Galil Medical);
- SurgiFrost® XL Surgical CryoAblation System (CryoCath Technologies; now Medtronic);
- The Isis™ cryosurgical unit (Galil Medical);
- Artic Front Advance)TM) and Artic Front Advance Pro™ and the Freezor Max™ (Medtronic)

## BENEFIT APPLICATION:

Coverage is subject to member's specific benefits. Group-specific policy will supersede this policy when applicable.

## CURRENT CODING:

**CPT Codes:**

| | |
|---|---|
| 33254 | Operative tissue ablation and reconstruction of atria, limited (e.g., modified MAZE procedure) |
| 33255 | Operative tissue ablation and reconstruction of atria, extensive (e.g., maze procedure); without cardiopulmonary bypass |

| | |
|---|---|
| 33256 | Operative tissue ablation and reconstruction of atria, extensive (e.g., maze procedure); with cardiopulmonary bypass |
| 33257 | Operative tissue ablation and reconstruction of atria, performed at the time of other cardiac procedure(s), limited (e.g., modified MAZE procedure) (List separately in addition to code for primary procedure.) |
| 33258 | Operative tissue ablation and reconstruction of atria, performed at the time of other cardiac procedure(s), extensive (e.g., maze procedure), without cardiopulmonary bypass (List separately in addition to code for primary procedure) |
| 33259 | Operative tissue ablation and reconstruction of atria, performed at the time of other cardiac procedure(s), extensive (e.g., maze procedure), with cardiopulmonary bypass (List separately in addition to code for primary procedure) |
| 33265 | Endoscopy, surgical; operative tissue ablation and reconstruction of atria, limited (e.g., modified MAZE procedure), without cardiopulmonary bypass |
| 33266 | Endoscopy, surgical; operative tissue ablation and reconstruction of atria, extensive (e.g., maze procedure), without cardiopulmonary bypass. |
| 33999 | Unlisted procedure, cardiac surgery |

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## POLICY HISTORY:

Adopted for Blue Advantage, January 2017
Available for comment February 6 through March 24, 2017
Medical Policy Group, May 2017
Available for comment May 15 through June 29, 2017
Medical Policy Group, July 2017
Medical Policy Group, June 2018
Medical Policy Group, May 2022
Medical Policy Group, June 2023
UM Committee, December 2023: Policy approved by UM Committee for use for Blue Advantage business.
Medical Policy Group, December 2024
UM Committee January 2025: Annual review of policy approved by UM Committee for use for Blue Advantage business.
Medical Policy Group, April 2025
UM Committee, April 2025: Annual review of policy approved by UM Committee for use for Blue Advantage business.

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*This medical policy is not an authorization, certification, explanation of benefits, or a contract. Eligibility and benefits are determined on a case-by-case basis according to the terms of the member's plan in effect as of the date services are rendered. All medical policies are based on (i) research of current medical literature and (ii) review of common medical practices in the treatment and diagnosis of disease as of the date hereof. Physicians and other providers are solely responsible for all aspects of medical care and treatment, including the type, quality, and levels of care and treatment.*

*This policy is intended to be used for adjudication of claims (including pre-admission certification, pre-determinations, and pre-procedure review) in Blue Cross and Blue Shield's administration of plan contracts.*