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: May 2022
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).*

Proprietary Information of Blue Cross and Blue Shield of Alabama
An Independent Licensee of the Blue Cross and Blue Shield Association

POLICY:

Effective for dates of service on and after June 10, 2019:

Blue Advantage will treat **the maze or modified MAZE procedure**, p**erformed 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 **the maze or modified MAZE procedure performed on a non-beating heart during cardiopulmonary bypass without concomitant cardiac surgery** as a **non-covered benefit** and as **investigational** for atrial fibrillation or atrial flutter. (CPT codes 33254 and 33256).

Blue Advantage will treat **the hybrid MAZE procedure** as a **covered benefit** as a stand-alone procedure in symptomatic patients who:

- have failed at least 2 class I or III antiarrhythmic medications AND a failed catheter based therapy. (CPT code 33999)

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

Blue Advantage will treat **minimally invasive, off-pump maze procedures** (i.e., modified MAZE procedures), including those done via mini-thoracotomy as a **non-covered benefit** and investigational. (CPT codes 33265 and 33266).

Blue Advantage will treat **the MAZE or modified MAZE procedure performed without cardiopulmonary bypass** as a **non-covered benefit** and as **investigational**. (CPT codes 33255 and 33258).

Effective for dates of service May 15, 2017, through June 9, 2019:

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 **the maze or modified MAZE procedure performed on a non-beating heart during cardiopulmonary bypass without concomitant cardiac surgery** as a **non-covered benefit** and **investigational** for atrial fibrillation or atrial flutter. (CPT codes 33254 and 33256).

Blue Advantage will treat **minimally invasive, off-pump maze procedures** (i.e., modified MAZE procedures), including those done via mini-thoracotomy as a **non-covered benefit** and **investigational**. (CPT codes 33265 and 33266).

Blue Advantage will treat **hybrid ablation** (defined as a combined percutaneous and thoracoscopic approach) as a **non-covered benefit** and **investigational**.

Blue Advantage will treat **the MAZE or modified MAZE procedure performed without cardiopulmonary bypass** as a **non-covered benefit** and **investigational**. (CPT codes 33255 and 33258).

Effective for dates of service prior to May 15, 2017:
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, drug resistant atrial fibrillation or atrial flutter.

Blue Advantage will treat **the maze or modified MAZE procedure performed on a non-beating heart during cardiopulmonary bypass without concomitant cardiac surgery** as a **non-covered benefit** for symptomatic, drug resistant atrial fibrillation or atrial flutter.

Blue Advantage will treat **minimally invasive, off-pump maze procedures** (i.e., modified MAZE procedures), including those done via mini-thoracotomy as a **non-covered benefit** and **investigational**.

Blue Advantage will treat **hybrid ablation** (defined as a combined percutaneous and thoracoscopic approach) as a **non-covered benefit** and **investigational**.

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 thoracoscopy with epicardial ablation. Following this procedure, an electrophysiologic study is performed percutaneously followed by endocardial ablation as directed by the results of electrophysiology. Most commonly, the electrophysiology study and endocardial ablation are done immediately after the thoracoscopy as part of a single procedure. However, some hybrid approaches perform the electrophysiology study and endocardial ablation, as directed by the electrophysiology study, on a separate day.

KEY POINTS:
The most recent literature review is through March 9, 2022.

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 and observational studies, some of which identify control groups. Relevant outcomes are overall survival, medication use, and treatment-related morbidity. Studies have reported high rates of maintaining sinus rhythm and less need for repeat ablations. Several single-arm case series of

minimally invasive epicardial ablation have reported on patients who had failed catheter ablation (CA). These case series 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 a RCTs, nonrandomized studies and an observational study. Relevant outcomes are overall survival, medication use, and treatment-related morbidity. The studies suggest that hybrid ablation procedures are associated with high rates of freedom from AF and may be considered if conservative treatments have failed. 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 2017, 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 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
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 is reasonable as a primary stand-alone procedure to restore sinus rhythm.	IIa	B
Surgical ablation for symptomatic persistent or long-standing persistent AF in the absence of structural heart disease is reasonable as a stand-alone procedure using the Cox-Maze III/IV lesion set compared with PVI alone	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, and Heart Rhythm Society (2019) issued joint guidelines in collaboration with the Society of Thoracic Surgeons on the 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
" AF catheter ablation may be reasonable in selected patients with symptomatic AF and HF with reduced left ventricular (LV) ejection fraction (HFrEF) to potentially lower mortality rate and reduce hospitalization for HF."	IIb	B-R

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

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

A 2017 expert consensus statement was developed by the HRS, European Heart Rhythm Association, and European Cardiac Arrhythmia Society. The statement was endorsed by the American College of Cardiology, American Heart Association, Asia Pacific Heart Rhythm Society, and Society of Thoracic Surgeons.

The following recommendations were made regarding concomitant surgical ablation in patients undergoing cardiac surgery for other purposes and who have symptomatic AF: (see Table 3).

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

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

COR: class of recommendation; LOE: level of evidence; NR: nonrandomized

a: For patients with symptomatic AF prior to initiation of antiarrhythmic therapy with Class I or III antiarrhythmic medication and indication for concomitant closed surgical ablation for AF, paroxysmal, persistent, and long-standing persistent (Class: IIa; LOE: B-NR).

The following recommendations were made regarding stand-alone surgical ablation in patients with symptomatic AF refractory or intolerant to at least one class 1 or 3 antiarrhythmic medication (see Table 4).

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

Recommendation[a]	COR	LOE
Paroxysmal:		
Stand-alone surgical ablation can be considered for patients who have not failed catheter ablation but prefer a surgical approach	IIb	B-NR
Stand-alone surgical ablation can be considered for patients who have failed one or more attempts at catheter ablation	IIb	B-NR
Persistent		
Stand-alone surgical ablation is reasonable for patients who have not failed catheter ablation but prefer a surgical approach	IIa	B-NR
Stand-alone surgical ablation is reasonable for patients who have failed one or more attempts at catheter ablation	IIa	B-NR
Longstanding		
Stand alone surgical ablation is reasonable for patients who have not failed catheter ablation but prefer a surgical approach	IIb	B-NR
Stand-alone surgical ablation is reasonable for patients who have failed one or more attempts at catheter ablation	IIb	B-NR

COR: class of recommendation; LOE: level of evidence

a: The recommendations noted that "it might be reasonable to apply the indication for stand-alone surgical ablation described above to patients being considered for hybrid surgical AF ablation.

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-NRb
"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-NRc

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 cleared for marketing by the U.S. Food and Drug Administration through the 510(k) process. They include:

- Epi-Sense Guided Coagulation System (Atricure, cleared for marketing in April 2021);
- Medtronic DiamondTemp™ System (Medtronic, cleared for marketing January 2021);
- Cobra Fusion Ablatoin System (AtriCure, cleared for marketing In February 2020);
- The Medtronic Cardioblate® System (Medtronic, Minneapolis, MN; cleared for marketing in January 2002);
- The Cardima Ablation System (Cardima, San Carlos, CA; cleared for marketing in January 2003);
- The Epicor™ Medical Ablation System (Epicor Medical , Sunnyvale, CA); cleared for marketing February 2004);
- The Isolator™ Transpolar™ Pen (AtriCure, West Chester, OH; cleared for marketing in June 2005);
- The Estech COBRA® Cardiac Electrosurgical Unit (Endoscopic Technologies, Danville, CA; cleared for marketing in January 2006);
- The Coolrail™ Linear Pen (AtriCure, West Chester, OH; cleared for marketing in March 2008).
- The Numeris® Guided Coagulation System with VisiTrax® (nContact Surgical, Morrisville, NC; cleared for marketing in February 2009).
- The EPi-Sense® Guided Coagulation System with VisiTrax® (nContact Surgical, Morrisville, NC; cleared for marketing in November 2012).

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, Irvine, CA; cleared for marketing in March 2002);
- The SeedNet™ System (Galil Medical; cleared for marketing in May 2005);
- SurgiFrost® XL Surgical CryoAblation System (CryoCath Technologies, Kirkland, QC, acquired by Medtronic; cleared for marketing in July 2006);
- The Isis™ cryosurgical unit (Galil Medical; cleared for marketing in March 2007)
- Artic Front Advance)TM) and Artic Front Advance Pro™ and the Freezer Max™ (Medtronic, cleared for marketing in June 2020)

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

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.