

MEDICAL POLICY

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| POLICY TITLE | OPEN AND THORACOSCOPIC APPROACHES TO TREAT ATRIAL FIBRILLATION AND ATRIAL FLUTTER (MAZE AND RELATED PROCEDURES) |
| POLICY NUMBER | MP 2.083 |

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| CLINICAL BENEFIT | <input checked="" type="checkbox"/> MINIMIZE SAFETY RISK OR CONCERN. <input checked="" type="checkbox"/> MINIMIZE HARMFUL OR INEFFECTIVE INTERVENTIONS. <input type="checkbox"/> ASSURE APPROPRIATE LEVEL OF CARE. <input type="checkbox"/> ASSURE APPROPRIATE DURATION OF SERVICE FOR INTERVENTIONS. <input checked="" type="checkbox"/> ASSURE THAT RECOMMENDED MEDICAL PREREQUISITES HAVE BEEN MET. <input type="checkbox"/> ASSURE APPROPRIATE SITE OF TREATMENT OR SERVICE. |
| Effective Date: | 9/1/2024 |

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I. POLICY

The maze or modified maze procedures, performed on a non-beating heart during cardiopulmonary bypass with concomitant cardiac surgery may be considered **medically necessary** for treatment of symptomatic, atrial fibrillation or flutter.

The use of an open maze or modified maze procedure performed on a non-beating heart without structural heart disease during cardiopulmonary bypass without concomitant cardiac surgery may be considered **medically necessary** for treatment of symptomatic, atrial fibrillation or flutter when **EITHER** of the following are met:

- Atrial fibrillation is refractory to at least one class I/III antiarrhythmic drugs, **OR**;
- Atrial fibrillation is refractory to catheter-based therapy having had at least one unsuccessful catheter-based ablation

Hybrid ablation (defined as a combined percutaneous and thoracoscopic approach) and minimally invasive, off-pump maze procedures (i.e., modified maze procedures), including those done via mini-thoracotomy, may be considered **medically necessary** for the treatment of symptomatic persistent atrial fibrillation or flutter when **ALL** below are met:

- Atrial fibrillation is refractory to at least one class I/III antiarrhythmic drugs and/or catheter-based therapy, **AND**;
- Both the surgeon and electrophysiologist agree that the procedure is an appropriate treatment

All other indications are considered **investigational**, as there is insufficient evidence to support a general conclusion concerning the health outcomes or benefits associated with this procedure.

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Policy Guidelines

Given the availability of less-invasive alternative approaches in the treatment of atrial fibrillation (AF) performing the maze procedure without concomitant cardiac surgery should rarely be needed.

Published studies on the maze procedure describe patients with drug-resistant AF and atrial flutter as having experienced their arrhythmias for an average of 7 or more years and having unsuccessful results with an average of 5 or more antiarrhythmic medications.

Cross-reference:

MP 1.127 Percutaneous Left-Atrial Appendage Closure Devices for Stroke Prevention in Atrial Fibrillation

II. PRODUCT VARIATIONS

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This policy is only applicable to certain programs and products administered by Capital BlueCross and subject to benefit variations as discussed in Section VI. Please see additional information below.

FEP PPO - Refer to FEP Medical Policy Manual. The FEP Medical Policy manual can be found at:

<https://www.fepblue.org/benefit-plans/medical-policies-and-utilization-management-guidelines/medical-policies>.

III. DESCRIPTION/BACKGROUND

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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 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 patients 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 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. Performed either by open surgical techniques or thoracoscopy, surgical ablation 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. It 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 the surgical treatment of drug-resistant AF, with a success rate of approximately 90%.

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 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 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 radiofrequency 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

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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 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 energy sources such as cryoablation and high-intensity ultrasound have 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 the use of 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 a hybrid procedure is that a combination of both techniques may result in a 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 on separate days, as directed by the electrophysiology study.

Regulatory Status

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 Food and Drug Administration

| Device | Manufacturer | 510(k) Date |
|--|---------------------|--------------------|
| Epi-Sense Guided Coagulation System | Atricure | April 2021 |

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|--|-------------------------|----------|
| Medtronic DiamondTemp™ System | Medtronic | Jan 2021 |
| Cobra Fusion Ablation System | AtriCure | Feb 2019 |
| Medtronic Cardioblate® System | Medtronic | Jan 2002 |
| Cardima Ablation System | Cardima | Jan 2003 |
| Epicor™ Medical Ablation System | Epicor Medical | Feb 2004 |
| Isolator™ Transpolar™ Pen | AtriCure | Jun 2005 |
| Estech COBRA® Cardiac Electrosurgical Unit | Endoscopic Technologies | Dec 2005 |
| Coolrail™ Linear Pen | AtriCure | Mar 2008 |
| Numeris® Guided Coagulation System with VisiTrax® | nContact Surgical | Feb 2009 |
| EPI-Sense® Guided Coagulation System with VisiTrax® | nContact Surgical | Nov 2012 |

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 Food and Drug Administration

| Device | Manufacturer | 510(k) Date |
|---|--------------------------------------|--------------------|
| Cryocare® Cardiac Surgery System | Endocare | Mar 2002 |
| SeedNet™ System | Galil Medical | May 2005 |
| SurgiFrost® XL Surgical CryoAblation System | CryoCath Technologies; now Medtronic | Jul 2006 |
| Isis™ cryosurgical unit | Galil Medical | Mar 2007 |
| Artic Front Advance™ and Arctic Front Advance Pro™ and the Freezer Max™ Cardiac Cryoablation Catheters | Medtronic | Jun 2020 |

Society Guidelines

The Society of Thoracic Surgeons 2017 clinical practice guideline for the surgical treatment of atrial fibrillation (AF):

Mitral Valve Operations and Concomitant Surgical Ablation:

- Surgical ablation for AF can be performed without additional risk of operative mortality or major morbidity and is recommended at the time of concomitant mitral operations to restore sinus rhythm. (Class I, Level A)

Aortic Valve and CABG Operations with Concomitant Ablation:

- Surgical ablation for AF can be performed without additional risk of operative mortality or major morbidity and is recommended at the time of concomitant isolated AVR, isolated CABG, and AVR plus CABG operations to restore sinus rhythm. (Class I, Level B nonrandomized)

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Stand-Alone Surgical Ablation for AF:

- 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 (Class IIA, Level 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 compared with PVI alone. (Class IIA, Level B nonrandomized)
- Surgical ablation for symptomatic AF in the setting of left atrial enlargement (≥ 4.5 cm) or more than moderate mitral regurgitation by PVI alone is not recommended. (Class III no benefit, Level C expert opinion)

IV. RATIONALE

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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 patients 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 a meaningful 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.

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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. However, The Society of Thoracic Surgeons 2017 clinical practice guidelines for the surgical treatment of atrial fibrillation (AF) supports this surgical treatment in certain circumstances.

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 (i.e., 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 20). The evidence is insufficient to determine that the technology results in an improvement in the net health outcome. However, The Society of Thoracic Surgeons 2017 clinical practice guidelines for the surgical treatment of atrial fibrillation (AF) supports this surgical treatment in certain circumstances.

V. DEFINITIONS

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ATRIAL FLUTTER is a cardiac arrhythmia marked by rapid (about three hundred beats per minute) regular atrial beating, and, usually, a regular ventricular response.

ATRIOVENTRICULAR (AV) NODE is an area of specialized cardiac muscle that receives the cardiac impulse from the sinoatrial (SA) node and conducts it to the AV bundle and then to the Purkinje fibers and the walls of the ventricles. The AV node is located in the septal wall between the left and right atria.

ATRIUM is the upper chamber of each half of the heart. Atria is the plural of atrium.

MYOCARDIUM is the middle layer of the walls of the heart, composed of cardiac muscle.

SINOATRIAL (SA) NODE is a specialized group of cardiac muscle cells in the wall of the right atrium at the entrance to the superior vena cava. These cells depolarize spontaneously and rhythmically to initiate normal heartbeats.

SUPRAVENTRICULAR TACHYCARDIA (SVT) is any cardiac rhythm with a rate exceeding one hundred (100) beats per minute that originates above the branching part of the atrioventricular bundle, that is, in the sinus node, atria, or AV junction.

TACHYCARDIA is an abnormally rapid heart rate, greater than one hundred (100) beats per minute.

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VI. BENEFIT VARIATIONS

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The existence of this medical policy does not mean that this service is a covered benefit under the member's health benefit plan. Benefit determinations should be based in all cases on the applicable health benefit plan language. Medical policies do not constitute a description of benefits. A member's health benefit plan governs which services are covered, which are excluded, which are subject to benefit limits, and which require preauthorization. There are different benefit plan designs in each product administered by Capital Blue Cross. Members and providers should consult the member's health benefit plan for information or contact Capital Blue Cross for benefit information.

VII. DISCLAIMER

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Capital BlueCross' medical policies are developed to assist in administering a member's benefits, do not constitute medical advice and are subject to change. Treating providers are solely responsible for medical advice and treatment of members. Members should discuss any medical policy related to their coverage or condition with their provider and consult their benefit information to determine if the service is covered. If there is a discrepancy between this medical policy and a member's benefit information, the benefit information will govern. If a provider or a member has a question concerning the application of this medical policy to a specific member's plan of benefits, please contact Capital BlueCross' Provider Services or Member Services. Capital BlueCross considers the information contained in this medical policy to be proprietary and it may only be disseminated as permitted by law.

VIII. CODING INFORMATION

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Note: This list of codes may not be all-inclusive, and codes are subject to change at any time. The identification of a code in this section does not denote coverage as coverage is determined by the terms of member benefit information. In addition, not all covered services are eligible for separate reimbursement.

Covered when medically necessary:

| Procedure Codes | | | | | | | | |
|-----------------|-------|-------|-------|-------|-------|-------|-------|--|
| 33254 | 33255 | 33256 | 33257 | 33258 | 33259 | 33265 | 33266 | |

| ICD-10-CM Diagnosis Codes | Description |
|---------------------------|--------------------------------|
| I48.0 | Paroxysmal atrial fibrillation |
| I48.1 | Persistent atrial fibrillation |

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| ICD-10-CM Diagnosis Codes | Description |
|----------------------------------|---|
| I48.11 | Longstanding persistent atrial fibrillation |
| I48.19 | Other persistent atrial fibrillation |
| I48.20 | Chronic atrial fibrillation, unspecified |
| I48.21 | Permanent atrial fibrillation |
| I48.3 | Typical atrial flutter |
| I48.4 | Atypical atrial flutter |
| I48.91 | Unspecified atrial fibrillation |
| I48.92 | Unspecified atrial flutter |

IX. REFERENCES

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87. Blue Cross Blue Shield Association Medical Policy Reference Manual. 7.01.14, Open and Thoracoscopic Approaches to Treat Atrial Fibrillation and Atrial Flutter (Maze and Related Procedures). June 2023

X. POLICY HISTORY

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| MP 2.083 | 07/20/2020 Minor Review. Changed “Open Maze or modified maze procedure on a non-beating heart during cardiopulmonary bypass without concomitant cardiac surgery”, “Hybrid ablation” and “Minimally invasive, off pump maze procedure” from investigational to medically necessary with criteria to align with The Society of Thoracic Surgeons 2017 Clinical Practice Guidelines. Description, Background and Rationale updated. References added. |
| | 09/27/2021 Consensus Review. No change to policy statement. References reviewed and updated. |
| | 11/22/2022 Consensus Review. Clarification for INV statement but no change to coverage. References and background updated, and coding reviewed. |
| | 12/14/2023 Consensus Review. No change to policy statement. Background and Rationale updated. References added. |
| | 06/11/2024 Consensus Review. No change to policy statements. References reviewed and updated. Added ICD-10 diagnosis codes I48.91 and I48.92. No procedure code changes. |

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