

Clinical UM Guideline

Subject: Maze Procedure
Guideline #: CG-SURG-05
Status: Reviewed

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Description

This document addresses the use of the Maze procedure as a curative surgical treatment of atrial fibrillation or flutter for individuals who do not respond to medical therapies. The Maze procedure, also known as the Cox-Maze procedure, involves creating sequential atriotomy lesions. These lesions interrupt potential re-entrant circuits and reestablish activation of the entire atrial myocardium, restoring its transport function. Lesions can be made using cryoablation, radiofrequency or less commonly, surgical incisions.

Note: Please see the following document for additional information regarding implantation of a left atrial appendage (LAA) occlusion device performed in conjunction with another open cardiac surgical procedure:

• SURG.00032 Patent Foramen Ovale and Left Atrial Appendage Closure Devices for Stroke Prevention

Note: Please see the following related documents for additional information:

- CG-MED-64 Transcatheter Ablation of Arrhythmogenic Foci in the Pulmonary Veins
- CG-SURG-55 Cardiac Electrophysiological Studies (EPS) and Catheter Ablation

Clinical Indications

Medically Necessary:

The Maze procedure is considered medically necessary for drug resistant atrial fibrillation or flutter.

The Maze procedure is considered **medically necessary** for individuals with highly symptomatic atrial fibrillation who require open heart surgery for valvular, ischemic, or congenital heart disease.

Not Medically Necessary:

The Maze procedure is considered not medically necessary for all other indications.

Coding

The following codes for treatments and procedures applicable to this document are included below for informational purposes. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement policy. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

When services may be Medically Necessary when criteria are met:

CPT	
33254	Operative tissue ablation and reconstruction of atria, limited (eg, modified maze procedure)
33255	Operative tissue ablation and reconstruction of atria, extensive (eg, maze procedure); without cardiopulmonary bypass
33256	Operative tissue ablation and reconstruction of atria, extensive (eg, maze procedure); with cardiopulmonary bypass
33257	Operative tissue ablation and reconstruction of atria, performed at the time of other cardiac procedure(s), limited (eg, modified maze procedure)
33258	Operative tissue ablation and reconstruction of atria, performed at the time of other cardiac procedure(s), extensive (eg, maze procedure), without cardiopulmonary bypass
33259	Operative tissue ablation and reconstruction of atria, performed at the time of other cardiac procedure(s), extensive (eg, maze procedure), with cardiopulmonary bypass
33265	Endoscopy, surgical; operative tissue ablation and reconstruction of atria, limited (eg, modified maze procedure), without cardiopulmonary bypass
33266	Endoscopy, surgical; operative tissue ablation and reconstruction of atria, limited (eg, maze procedure), without cardiopulmonary bypass
ICD-10 Procedure	
	For the following codes when specified as the maze procedure:
02560ZZ-02564ZZ	Destruction of right atrium [by approach; includes codes 02560ZZ, 02563ZZ, 02564ZZ]
02570ZZ-02574ZZ	Destruction of left atrium [by approach; includes codes 02570ZZ, 02573ZZ, 02574ZZ]

02560ZZ-02564ZZ Destruction of right atrium [by approach; includes codes 02560ZZ, 02563ZZ, 02564ZZ]
02570ZZ-02574ZZ Destruction of left atrium [by approach; includes codes 02570ZZ, 02573ZZ, 02574ZZ]
02580ZZ-02584ZZ Destruction of conduction mechanism [by approach; includes codes 02580ZZ, 02583ZZ,

02584ZZ]

ICD-10 Diagnosis

148.0-148.92 Atrial fibrillation and flutter

When services are Not Medically Necessary:

For the procedure codes listed above when criteria are not met or for all other diagnoses not listed.

Discussion/General Information

In a healthy heart, cardiac muscle fibers located in the atria (top chambers of the heart) conduct a single impulse which travels through the heart creating a normal heart beat. Atrial fibrillation (AF) occurs when the muscle fibers send multiple erratic impulses

through the atria resulting in a rapid, disorganized heart rate. AF is the most common persistent arrhythmia; prevalence increases with age. Approximately 570,000 individuals in the United States have atrial arrhythmia at any time with 89,000 new cases annually (Badhwar, 2017). Long-term risks include increased incidence of stroke, heart failure and premature mortality (Saltman, 2009; Wu, 2017).

The Maze procedure is the "gold standard for surgical treatment of atrial fibrillation" (Calkins, 2012; Khiabani, 2022; Saltman, 2009; Weimar, 2011) and is the most effective curative surgical treatment of AF for individuals who do not respond to medical therapies. This open surgical procedure is frequently combined with other cardiac surgeries on a non-beating heart during cardiopulmonary bypass and involves complex, sequential atriotomy incisions. The "maze-like" incision pattern and resulting scar tissue do not conduct electrical activity, thus impeding propagation of the misfired impulses that result in abnormal atrial contraction characteristic of AF. Since its development, modifications have been made to the original Maze procedure to improve efficacy and decrease operative time, creating the now standard Cox Maze III procedure. Long-term follow-up from various studies have reported the efficacy of the Maze procedure, indicated by establishment of normal sinus rhythm, may range from 70% to 96% (Saltman, 2009; Khiabani, 2022). Although operative risk is also similar for aged individuals (Ad, 2013), long-term benefit has been found to decrease with increasing age (Bakker, 2013). Surgical ablation using the Maze technique is most commonly used as a concomitant procedure during valve or coronary revascularization procedures with good clinical outcomes (Badhwar, 2017; Cui, 2008; Liu, 2010).

There are multiple surgical ablation techniques to treat atrial fibrillation. Many of these procedures involve less extensive ablation than the Maze procedure. The 2017 expert consensus statement by the Heart Rhythm Society (HRS); European Heart Rhythm Association (EHRA), the European Cardiac Arrhythmia Society (ECAS), the Asia Pacific Heart Rhythm Society (APHRS), and the Latin American Society of Cardiac Stimulation and Electrophysiology (SOLAECE) recommends that only procedures which include ablation of the RA and LA isthmus be referred to as Maze procedures (Calkins, 2018).

Kong and colleagues (2010) performed a meta-analysis of randomized trials comparing the efficacy of surgical Maze procedures performed concomitantly with cardiac surgery compared to cardiac surgery alone for the treatment of AF. Nine randomized studies using Cox-Maze III or modified Maze ablation procedures enrolled a total of 472 individuals. Three studies did not report freedom from AF within 12 months and one study enrolled participants with paroxysmal AF. The five remaining studies suggest that the "surgical Maze procedure greatly increases the odds of freedom from AF within 12 months post-procedure. The estimated odds ratio is 5.22 (95% confidence interval [CI], 1.71 to 15.88)" (Kong, 2010). There was no significant difference in operative mortality rate of 4.0% in the treatment group versus 3.3 % in the control group. There was also no significant difference in the overall rate of major complications with the treatment group experiencing 24.4% and the control group with a complication rate of 24.9%. There was no significant difference in freedom from AF and anti-arrhythmic drugs (AADs) in participants treated with cardiac surgery alone (51.9%) compared to those treated with the Maze procedure and a concomitant cardiac surgery (53.3%).

The use of radiofrequency energy and cryothermy to create atrial lesions, referred to as the Cox Maze III/IV procedure, has largely replaced the scalpel incisional technique used in the traditional Maze procedure (Ad, 2017; Calkins, 2018). The resulting return of sustained sinus rhythm has been between 44% and 92% in various studies (Beukema, 2008). Khargi and colleagues (2007) performed a systematic review of 48 eligible studies to compare the surgical treatment utilizing alternative energy sources (Group 1) with the classical cut-and-sew Cox-Maze III procedure (Group 2). The authors noted an unexpected and significant difference in mean age of 6.2 years between the cohorts (61.2 years versus 55.0 years, respectively). In addition, AF alone (19.3%) was the primary indication for Group 2, compared to 1.6% of the participants in Group 1. After adjustment for the type of arrhythmia and type of surgery, there was no significant difference in the post-operative sinus rhythm conversion rate between the two groups (p=0.260) suggesting that alternative energy sources are a feasible option for performing surgical incisions in the Cox-Maze procedure.

Weimar and colleagues (2011) reported results from a case series of 100 participants treated with the Cox-Maze procedure IV (CMP-IV), which is the modified Cox-Maze III procedure utilizing bipolar radiofrequency and cryoenergy, to create the linear ablation lines. The CMP-IV procedure included isolation of the pulmonary vein with either the box lesion or the non-box lesion set. The mean follow-up was 17 ± 10 months and freedom from AF at 6-, 12- and 24-months was 93%, 90% and 90% respectively. In addition, freedom from AF along with discontinuing antiarrhythmic medication was 82%, 82% and 84% at 6-, 12- and 24-months. The overall 30-day mortality rate was 1%. Subset analysis at 1-year for the complete box lesion set (n=78), resulted in 96% freedom from AF and 86% had stopped antiarrhythmic drugs. Participants treated with the non-box lesion set (n=22) had 79% freedom from AF and 47% were no longer taking antiarrhythmic drugs at 1-year. Authors conclude that the less invasive CMP-IV has a high success rate.

Osmancik and associates reported on the long-term clinical outcomes of individuals who participated in a prospective, randomized multicenter clinical trial assessing cardiac surgery with ablation for AF compared to cardiac surgery alone (2019). The PRAGUE-12 trial included individuals with AF and an indication for cardiac surgery were randomly assigned to surgery combined with left atrial surgical ablation (SA group, n=108) or to the surgery without ablation group (control group, n=99). Participants were followed for 5 years and at the end of the follow-up, clinical outcomes were analyzed against the primary endpoint, which was a composite of cardiovascular death, stroke, hospitalization for heart failure, or severe bleeding. The primary endpoint occurred in 42.6% (n=46) of the SA group and in 61.6% (n=61) of the control group. While all components of the primary endpoint were reported less often in the SA group, the differences did not reach statistical significance. However, the incidence of stroke, a secondary endpoint, and AF recurrence was significantly reduced in the SA group.

The effectiveness of the Cox-Maze IV procedure to provide freedom from atrial tachyarrhythmia after up to 10 years post-procedure was assessed in a single center retrospective study (Khiabani, 2022). Individuals who underwent either biatrial or left sided Cox-Maze (n=853). Freedom from atrial tachyarrhythmia (AF, atrial flutter, or atrial tachycardia lasting longer than 30 seconds) with or without the use of antiarrhythmic drugs at 1, 3, 5, 8, and 10 years was 92% (552/598), 88% (340/385), 84% (213/253), 83% (91/110), and 77% (67/87), respectively. When the analysis is limited to reviewing freedom from atrial tachyarrhythmia without the use of antiarrhythmic drugs at 1, 3, 5, 8, and 10 years, the numbers decrease to 84% (505/598), 80% (309/385), 71% (180/253), 68% (75/110), and 61% (53/87), respectively. Those individuals who maintained a sinus rhythm at 10 years experienced better survival rates compared to those who had at least 1 atrial tachyarrhythmia episode (84% (95% CI, 80%-89%) versus 77% (95% CI, 71%-84%); respectively, log-rank test, p=0.03).

Approximately 18 to 28% of individuals with hypertrophic cardiomyopathy (HCM), a common genetic heart disease, have persistent AF (Meng, 2021; Ommen, 2020). This population have poor tolerance of AF and individuals with HCM and AF have a higher mortality of cardiovascular and non-cardiovascular disease than individuals with HCM without AF. The combination of Cox-Maze with septal myectomy appears to result in a lower AF recurrence and improved survival (Bakir, 2022; Meng, 2021; Seco, 2022).

Other Considerations

On January 25, 2002, the FDA approved the Medtronic Cardioblate® System (Medtronic Inc., Minneapolis, MN) which uses radiofrequency energy to ablate cardiac tissue. On January 29, 2003, the Cardima® Ablation System (Cardima, Inc. Fremont, CA) received FDA approval as substantially equivalent to the Medtronic device, amongst others which are also FDA-approved for performing ablation of cardiac tissue. On December 14, 2011, the FDA approved the Atricure Synergy Ablation System (AtriCure, Inc., Mason, OH) for the treatment of atrial fibrillation. The Atricure system is the only system approved that is specifically labeled for

surgical ablation of atrial fibrillation (Calkins, 2018).

In the 2014 Guideline from the American Heart Association (AHA), the American College of Cardiology (ACC) and the HRS for the management of individuals with atrial fibrillation, the following recommendations for surgical Maze procedures were issued:

An AF surgical ablation procedure is reasonable for selected patients with AF undergoing cardiac surgery for other indications. [Class IIa recommendation; Level of Evidence: C]

A stand-alone AF surgical ablation procedure may be reasonable for selected patients with highly symptomatic AF not well managed with other approaches. [Class IIb recommendation; Level of Evidence: B]

The 2017 Society of Thoracic Surgeons (STS) Clinical Practice Guidelines on the surgical treatment of atrial fibrillation includes the following recommendations regarding surgical ablation in concomitant cardiac surgery and as a stand-alone procedure:

Surgical ablation for atrial fibrillation (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)

Surgical ablation for AF can be performed without additional operative risk of mortality or major morbidity, and is recommended at the time of concomitant isolated aortic valve replacement, isolated coronary artery bypass graft surgery, and aortic valve replacement plus coronary artery bypass graft operations to restore sinus rhythm. (Class I, Level B nonrandomized)

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 recommendation, Level of evidence B randomized)

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 recommendation, Level of evidence B nonrandomized)

In 2020, the AHA/ACC published a guideline on the diagnosis and treatment of HCM. The guideline supports that the Maze procedure combined with other surgical treatments noting:

In patients with symptomatic obstructive HCM who have associated cardiac disease requiring surgical treatment (e.g., associated anomalous papillary muscle, markedly elongated anterior mitral leaflet, intrinsic mitral valve disease, CAD, valvular aortic stenosis), surgical myectomy performed by experienced operators provides the opportunity to correct all of the structural/anatomic issues with a single procedure. Similarly, for patients with paroxysmal AF, intraoperative pulmonary vein isolation or Maze procedure can also be added to septal myectomy.

Definitions

Atrial fibrillation (AF): A condition where there is disorganized electrical conduction in the atria, resulting in ineffective pumping of blood into the ventricle.

Arrhythmia: An alteration in rhythm of the heartbeat either in time or force.

Atriotomy: A surgical incision into the atrium of the heart.

Maze Ablation: Original name of the procedure is Maze procedure. The name of the procedure has evolved to Cox-Maze. There are also variations of this procedure labelled III or IV. These terms all refer to the same procedure with variations. Maze ablation, includes, at minimum, the following incisions or lines:

- Superior vena cava (SVC) to inferior vena cava (IVC)
- · IVC to the tricuspid valve
- Isolation of the pulmonary veins (PVs)
- · Isolation of the posterior left atrium (LA)
- Mitral valve (MV) to the PVs
- Management of the LA appendage

Sinus rhythm: A normal heartbeat, both with respect to the heart rate and rhythm. Heart rate is usually between 60 and 100 beats per minute.

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History

Status	Date	Action	
Reviewed	05/11/2023	Medical Policy & Technology Assessment Committee (MPTAC) review. Updated Description, Discussion and References sections.	
	10/27/2022	Updated the Description section to add "SURG.00032 Patent Foramen Ovale and Lef Atrial Appendage Closure Devices for Stroke Prevention" as a related policy.	t
Reviewed	05/12/2022	MPTAC review. Updated Description, Discussion, Definitions and References sections	s.
Reviewed	05/13/2021	MPTAC review. Updated Discussion and References sections. Reformatted Coding section.	
Reviewed	05/14/2020	MPTAC review. Updated Discussion and References sections.	
Reviewed	06/06/2019	MPTAC review. Updated Discussion and References sections.	
Reviewed	07/26/2018	MPTAC review. Updated Discussion and References sections.	
	05/03/2018	The document header wording updated from "Current Effective Date" to "Publish Date	∍."
Reviewed	08/03/2017	MPTAC review. Updated Discussion, Definition and References sections.	
Reviewed	08/04/2016	MPTAC review. Updated Websites. Removed ICD-9 codes from Coding section.	
Reviewed	08/06/2015	MPTAC review. Updated Discussion and References sections.	
Reviewed	08/14/2014	MPTAC review. Updated Description, Discussion and References sections. Definition section added.	
Reviewed	08/08/2013	MPTAC review. Discussion section and references updated.	
Reviewed	08/09/2012	MPTAC review. Discussion section and references updated.	
Reviewed	08/18/2011	MPTAC review. Discussion/Background section and references updated.	
Reviewed	08/19/2010	MPTAC review. Discussion/Background section and references updated.	
Reviewed	08/27/2009	MPTAC review. Discussion section and references updated.	
Revised	08/28/2008	MPTAC review. Added medically necessary statement for individuals with highly	
		symptomatic atrial fibrillation who require open heart operations for valvular, ischemic.	
		or congenital heart disease. Added not medically necessary statement. Discussion	,
		section and references updated.	
Reviewed	01/01/2008	Updated coding section with 01/01/2008 CPT changes.	
Reviewed	08/23/2007	MPTAC review. References updated. Coding updated; removed CPT 33253 deleted	
		12/31/2006.	
Reviewed	09/14/2006	MPTAC review. References and coding updated.	
Revised	09/22/2005	MPTAC review. Revision based on Pre-merger Anthem and Pre-merger WellPoint	
		Harmonization.	
Pre-Merger Or	ganizations	Last Review Date Document Number Title	
Anthem, Inc.		No document	
WellPoint Health Networks, Inc.		09/23/2004 3.04.02 Maze Procedure	
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Federal and State law, as well as contract language, and Medical Policy take precedence over Clinical UM Guidelines. We reserve the right to review and update Clinical UM Guidelines periodically. Clinical guidelines approved by the Medical Policy & Technology Assessment Committee are available for general adoption by plans or lines of business for consistent review of the medical necessity of services related to the clinical guideline when the plan performs utilization review for the subject. Due to variances in utilization patterns, each plan may choose whether to adopt a particular Clinical UM Guideline. To determine if review is required for this Clinical UM Guideline, please contact the customer service number on the member's card.

Alternatively, commercial or FEP plans or lines of business which determine there is not a need to adopt the guideline to review services generally across all providers delivering services to Plan's or line of business's members may instead use the clinical guideline for provider education and/or to review the medical necessity of services for any provider who has been notified that his/her/its claims will be reviewed for medical necessity due to billing practices or claims that are not consistent with other providers, in terms of frequency or in some other manner.

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