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Subject **Maze Procedure**

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Coverage Policy

CIGNA covers the surgical Maze procedure, performed during cardiopulmonary bypass with or without concomitant cardiac surgery, as medically necessary for medically refractory, intermittent (i.e., paroxysmal or persistent) or continuous (i.e., permanent), symptomatic atrial fibrillation when rhythm control is considered essential.

CIGNA does not cover a minimally invasive off-pump Maze procedure (e.g., pulmonary vein isolation via mini-thoracotomy) for any indication including the treatment of atrial fibrillation because it is considered experimental, investigational or unproven.

General Background

Therapeutic options for atrial fibrillation (AF) include medications (i.e., rate and rhythm control medications, anticoagulants), cardioversion, catheter ablation and surgical ablation. Treatment decisions for AF are based on the type and duration of AF, the severity and type of symptoms, associated cardiovascular disease, patient age, associated medical conditions, short-term and long-term treatment goals, and pharmacological and nonpharmacological therapeutic options. These factors prevent development of global recommendations for a standard treatment in all patients (Gillinov, 2007; Fuster, et al., 2006).

Surgical Maze Procedure

The inconsistent efficacy and potential toxicity of antiarrhythmic drug therapies has resulted in exploration of a wide spectrum of alternative nonpharmacological therapies for the prevention and control of AF. Years of research in the 1980s found critical elements necessary to cure AF surgically, including techniques that entirely eliminate macroentrant circuits in the atria while preserving sinus node and atrial transport functions. The surgical approach was based on the hypothesis that reentry is the predominant mechanism responsible for the development and maintenance of AF, leading to the concept that atrial incisions at critical locations would create barriers to conduction and prevent sustained AF. The procedure developed to accomplish these goals was based on the concept of a geographical Maze, accounting for the term "Maze" procedure used to describe this type of cardiac operation (Fuster, et al., 2006).

The surgical Maze procedure is the gold standard for surgical treatment of AF. As it is an open-chest procedure, surgical Maze is generally performed on patients needing open-heart surgery for other issues, such as valve replacement or repair or coronary artery bypass (CABG). This is called "concomitant surgery," meaning that it is done along with another procedure. It is performed on either a stopped or a beating heart. Since its introduction, the Maze procedure has gone through many iterations (e.g., Maze I, II, and III) using cut-and-sew techniques. The final iteration of this procedure, the Cox-Maze III, has become the gold standard for the surgical treatment of AF. In late follow-up from experienced centers, over 90% of patients have been reported to be free of symptomatic AF. Success rates of around 95% over 15 years of follow-up have been reported in patients undergoing mitral valve surgery. Other studies suggest success rates around 70%.

The modified surgical ablation Maze procedure, or Cox Maze IV, evolved from the Cox Maze III cut-and-sew procedure. Instead of using incisions, a surgical ablation energy source is used to create a conduction block of scar tissue to stop the errant electrical signals. The ablation lines have been created using a variety of energy sources including radiofrequency energy, microwave, cryoablation, laser and high-intensity focused ultrasound. The surgical ablation version of the maze procedure is generally faster than the Cox Maze III procedure and has reports of over 90% of patients free from symptomatic AF at one year. Risks include death (less than 1% when performed as an isolated procedure), the need for permanent pacing (with right-sided lesions), recurrent bleeding requiring reoperation, impaired atrial transport function, delayed atrial arrhythmias (especially atrial flutter), and atrioesophageal fistula (Saltman, et al., 2009; Nussmeier, et al., 2009; Calkins, et al., 2007; ECRI, 2007; Lall, et al., 2007; Khargi, et al., 2005, 2007; Fuster, et al., 2006).

U.S Food and Drug Administration (FDA)

The Maze procedures are not subject to regulation by the FDA. The devices used to perform the procedure are regulated by the FDA.

Literature Review

Surgical Maze Procedure

The peer-reviewed medical literature includes both relatively large retrospective and prospective studies documenting the safety and efficacy of the surgical Maze procedure performed during cardiopulmonary bypass with or without concomitant cardiac surgery. Study results suggest that the Maze procedure adds little or no additional risk when performed simultaneously with other open heart surgeries such as valvular repair or replacement. The Maze III procedure was used most commonly; however, several studies reported modifications to this procedure, such as use of cryoprobes or thermal probes for creation of ablation lines. Outcome measures in the studies vary. Some studies measure atrial function, primarily using echocardiography. Duration of follow-up in the studies is highly variable; some studies report outcomes after several months, while others follow patients for a number of years. Most studies do not describe ongoing medical therapies; thus, it is not possible to determine whether patients were still receiving antiarrhythmic medications or anticoagulants postoperatively (VonOppell, et al., 2009; Albrecht, et al., 2009; Wang, et al., 2009; Louagie, et al., 2009; Lönnerholm, et al., 2008; Srivastava, et al., 2008; Doty, et al., 2007; Stulak, et al., 2007a; Stulak, et al., 2007b; Gillinov, et al., 2006; Melby, et al., 2006; Gaynor, et al., 2005; Lee, et al., 2005; Bando, et al., 2002; Cox, et al., 2000).

Meta-Analysis: To assess the efficacy and safety of the surgical Maze and modified Maze procedures for the elimination of AF, Kong et al. (2010) conducted a meta-analysis of randomized clinical trials comparing the surgical Maze or modified Maze procedure in the setting of cardiac surgery with nonablative, medical therapy for the treatment of atrial fibrillation (AF). Primary outcomes were either freedom from AF within 12 months post procedure off antiarrhythmic drug (AAD), or freedom from AF while taking an AAD. Secondary outcomes included operative mortality, all-cause mortality, hospital length of stay, and postoperative complications. The

meta-analysis included nine randomized controlled trials (n=472, of which 249 underwent a Maze procedure and 213 underwent referral surgery alone). The surgical ablation techniques varied among the nine studies in terms of lesion sets, epicardial versus endocardial approaches, and left atrial versus biatrial patterns, energy sources, and technical equipment. Only one study performed the classic Cox-Maze III cut-and-sew operation. A single study used cryoablation, and a single study used microwave ablation. The mean cardiopulmonary bypass time across all nine trials was 128.3 minutes for the patients who underwent a concomitant Maze procedure compared with only 103.8 minutes for the patients in the control groups. The surgical Maze procedure significantly increased the odds of freedom from AF within 12 months compared with cardiac surgery alone. There was significant heterogeneity among the trials for freedom from AF ($p=0.003$). Among the two studies that fully reported AAD use, there was no evidence of improved survival free from AF and AAD therapy. Among patients with valvular AF, surgical Maze procedures are associated with a decrease in AF one year post procedure without significant increase in mean length of hospital stay, perioperative complications, operative, or all-cause mortality. Large controlled trials defining rates of freedom from AF without AADs postprocedure, are still needed to evaluate outcomes and determine the appropriate role for surgical Maze procedures in the management of AF. The authors stated that their study highlights the need for improved standardization and uniformity of reporting to enable more reliable evaluations of these surgical procedures.

In a systematic review, Khargi et al. (2007) evaluated the efficacy of the alternative sources of energy (radiofrequency-microwave and cryoablation; (group I) and the classical “cut and sew” Cox-Maze III (group II), which states a 97–99% SR success rate in the surgical treatment of AF. Clinical studies on the surgical treatment of AF citing the clinical outcome, including the postoperative SR, were included. Forty-eight studies were included comprising 3832 patients: 2279 in group I and 1553 in group II. The unavailability of prospective randomized studies on the surgical treatment of AF was a drawback of this systemic review. The authors concluded that a SR conversion rate of 97–99% after the “cut and sew” technique was never reported in the included studies. Alternative sources of energy were predominantly used as concomitant surgical procedures in older and more morbid patients, who often had permanent AF. The alternative sources of energy were not associated with an increased postoperative pacemaker implantation or an excessive 30-day mortality rate. The “cut and sew” Cox-Maze III was conducted in younger patients, more often to treat paroxysmal and lone AF. After correction for these variations, the postoperative SR conversion rates for both groups did not differ significantly. The authors could not identify any significant difference in the postoperative SR conversion rates between the classical “cut and sew” and the alternative sources of energy, which were used to treat AF.

In a meta-analysis, Reston and Shuhaiber (2005) studied whether the Maze procedure, including variants with different incision patterns and energy sources, leads to improvement in patient-oriented outcomes. Rates of stroke and mortality following the Maze procedure were the primary outcomes. Secondary outcomes included restoration of SR, need for a permanent pacemaker, and postoperative bleeding. Four randomized controlled trials (RCT) and six retrospective comparative studies met criteria. The authors concluded that surgical eradication of chronic AF may reduce the incidence of stroke with a small increased risk for placement of a pacemaker. Alternate energy sources, such as radiofrequency ablation, minimizes the risk of bleeding associated with the traditional cut-and-sew technique. Reported limitations of this meta-analysis are the small number of RCTs and the small size of the evidence base. The authors stated larger RCTs are needed to confirm these findings and to evaluate quality of life and survival.

The surgical treatment of AF using an alternate source of energy (group 1) or the classical Cox-Maze III technique (group 2) was analyzed in a systematic review of the literature by Khargi et al. (2005). Forty-eight studies were included in the review, comprising 3832 patients—2279 in group 1 and 1553 in group II. The authors could not identify any significant difference in the postoperative SR conversion rates between the two groups. There were no randomized controlled trials in this review.

Wong et al. (2006) evaluated the usefulness of the Maze procedure among patients with AF undergoing mitral valve surgery. Seven matched-controlled and four randomized trials were identified. After 2–8 years of follow-up in matched-controlled studies, odds ratio and 95% confidence interval (CI) for AF-free, embolic events-free, and long-term survival for those treated with Maze were 12.51 (95% CI: 9.18–17.03), 9.35 (95% CI: 5.11–17.13), and 2.27 (95% CI: 1.21–4.27), respectively. Correspondingly, after 1–1.5 years of follow-up in randomized trials, they were 9.01 (95% CI: 4.21–19.3), 5.19 (95% CI: 0.50–53.6), and 0.49 (95% CI: 0.12–1.93), respectively. The authors concluded that the addition of the Maze procedure to mitral valve surgery was more likely to maintain patients in SR and may lower embolic events, including stroke, but did not necessarily improve long-term survival.

Minimally Invasive Maze Procedures

Despite its high success rate, the Maze procedure has not been widely adopted other than for patients undergoing cardiac surgery because of the need for cardiopulmonary bypass. Therefore, numerous minimally invasive, transthoracic, endoscopic, off-pump procedures are being investigated to treat AF.

While the open-chest Maze surgery is sometimes done as a standalone procedure on patients with AF only, more often these AF only cases are performed by a minimally-invasive version of the Maze procedure called the mini Maze procedure. It evolved from the Cox Maze III procedure and is performed on a beating heart without opening the chest. While patients with paroxysmal AF have been considered the best candidates for the mini Maze procedure, recent enhancements have allowed the procedure to be used for patients with persistent and longstanding persistent AF, sometimes referred to as chronic or permanent AF. A new version of the mini Maze procedure is the total thorascopic Maze. Reported results for the mini Maze procedure have varied by center due to differences in measuring success and because the procedure keeps evolving. In addition, unlike catheter ablation, which has had a predominant energy source that has been relatively consistent from center to center, the mini Maze procedure has involved a wide variety of energy sources and devices that have produced widely-varying results (Morady, et al., 2011; Nussmeier, et al., 2009; Cheema, et al., 2009; Gillinov, 2007; ECRI, 2007; Bakir, et al., 2007; Fuster, et al., 2006; Gehi, et al., 2006; Pruitt, et al., 2006; Wolf, et al., 2005; Gillinov, et al., 2004).

The minimally invasive, video-assisted thoracoscopic surgical technique (e.g., Wolf MiniMaze™ Procedure) enables surgical treatment of AF through an epicardial (on the outside of the heart) approach on a beating heart. The procedure uses a bipolar RF ablation device, which can create bilateral, transmural, linear lesions around the atrial cuff of the left and right pulmonary veins without requiring a sternotomy or open heart surgery. The excision of the left atrial appendage, the major source of thromboemboli associated AF, is incorporated into this minimally invasive procedure. The procedure also includes the removal of the ligament of Marshall, which is thought to be a cause of AF. The closed-chest procedure is performed through two small incisions on either side of the chest which allows the surgeon to manipulate the instruments through a thoracoscope. Technically the Wolf procedure is not a true Maze procedure, as the number of incisions is too few to warrant the term "Maze"; it is more similar to the pulmonary vein isolation via catheter ablation but with the additional step of removing the left atrial appendage (Nussmeier, et al., 2009; ECRI, 2007; Wolf, et al., 2005).

The Ex-Maze has been proposed as a minimally-invasive treatment for patients with paroxysmal, persistent, or permanent AF. The Ex-Maze pattern is modeled after the "cut and sew" Maze. The Ex-Maze has been performed during concomitant cardiac surgical procedures and as a minimally invasive stand-alone procedure. During the Ex-Maze procedure, comprehensive (full Maze), bi-atrial lesion patterns are made epicardially (while the heart is beating) and the patient is off bypass. A lesion creation device (nContact Surgical Inc, Morrisville, NC) and the development of paracardioscopy provide the technology required to minimally invasively create the Ex-Maze pattern on a beating heart. The procedure involves placing a small port in the abdomen through the diaphragm and into the adjoining pericardial space allowing the surgeon direct access to the back of the heart. This new approach is called paracardioscopy. Combined with a similar small port access on the patient's right side, the surgeon has direct access to the entire backside of the heart. The ability to visualize the back of the heart allows the precise creation of complete conduction blocking patterns. The ablation device uses unipolar radiofrequency energy with vacuum-maintained contact and suction-controlled saline perfusion for uniform energy transmission and transmural lesion development. Suction encourages the electrode coil in approximation with the epicardial surface, thus making consistent contact. There is insufficient evidence in the medical literature to indicate the safety, efficacy and long-term outcomes with the Ex-Maze procedure. Long-term follow-up to evaluate the clinical effectiveness of this procedure is ongoing (Kiser, et al., 2007).

Literature Review

Minimally Invasive Maze Procedures

Evidence in the peer-reviewed, published scientific literature is insufficient to allow strong conclusions in terms of safety and long term efficacy of minimally invasive approaches for the treatment of AF. Published evidence evaluating these minimally invasive procedures is primarily in the form of single center retrospective or prospective case series with few controlled clinical trials. Generally, the outcomes of the studies demonstrate improvement in AF following ablation. However, comparison between clinical studies is difficult and limited by heterogeneous study populations, use of different lesion sets and energy sources, differences in type of designs and lack of standardized outcome measures and definitions of success. Follow-up time varies across studies as

well as definition of procedure success used to assess clinical outcomes. Furthermore, there is no clear consensus among authors regarding patient selection criteria. Further scientific research, involving well-designed controlled clinical trials with long-term net health outcome data, are still needed to clearly define and establish a role for minimally invasive off-pump Maze procedures for the treatment of AF. The data are insufficient to reach conclusions about the relative effectiveness of these procedures compared to the classic surgical Maze procedure for the treatment of AF or to catheter-based ablation.

In a case series study, Spezial et al. (2010) reported their initial experience in a group of 46 patients with paroxysmal or persistent AF who were refractory to medical treatment or had arrhythmia recurrences after endocardial ablation and underwent epicardial radiofrequency pulmonary veins isolation by a minimally invasive, monolateral thoracoscopic approach. There were no deaths and one serious complication due to severe bleeding requiring conversion to median sternotomy. At the six-month follow-up (Holter monitoring), 40 patients (87%) were in stable sinus rhythm. Of the six recurrences, five occurred in patients with persistent AF and one in a patient with paroxysmal AF ($p < 0.01$). The authors reported that additional studies based on longer follow-up periods and more objective methods of evaluation are warranted. If confirmed, the results may prompt clinicians to consider their approach as an alternative to transcatheter ablation, although the relative efficacy of percutaneous and minimally invasive techniques should be assessed by prospective randomized trials.

Edgerton et al. (2010) performed a prospective, nonrandomized study of consecutive patients ($n=52$) with symptomatic paroxysmal AF undergoing a video-assisted, minimally invasive surgical ablation procedure. The procedure consisted of bilateral, epicardial pulmonary vein isolation with bipolar radiofrequency, partial autonomic denervation, and selective excision of the left atrial appendage (LAA). Preoperative patient conditions varied among the patients consisting of AF duration < 6 mo, unsuccessful antiarrhythmic drug (AAD) therapy, warfarin intolerance/noncompliance, previous catheter ablation, preoperative pacemaker, previous cardiac surgery and coronary artery disease. Definition of procedure success consisted of no episodes of AF/left atrial flutter/atrial tachycardia > 30 seconds. Continuous telemetric monitoring was performed throughout the hospital stay and a 12-lead electrocardiogram was obtained 1, 3, 6, and 12 months after discharge. Long-term monitoring by either a 24-hour Holter monitor, 2- to 3-week event monitoring, or interrogation of an implanted pacemaker was obtained at 6 and 12 months. Fifty patients at six months and 47 patients at 12 months completed the follow-up symptom surveys. On long-term monitoring, freedom from atrial fibrillation/flutter/tachycardia was 86.3% (44/51) and 80.8% (42/52) at 6 and 12 months, respectively. Antiarrhythmic drugs were stopped in 33 of 37 patients and warfarin in 30 of 37 of the patients in whom ablation was successful at 12 months. Freedom from symptoms attributed to atrial fibrillation/flutter/tachycardia was 78.0% (39/50) at 6 months and 63.8% (30/47) at 12 months. The LAA was excised or stapled in 44 (88.0%) of 50 patients. LAA exclusion was not performed if the operative surgeon deemed the LAA anatomy unsafe for endoscopic staple exclusion. No operative deaths or major adverse cardiac events. Three patients required new postoperative permanent pacemaker placement. Two patients underwent additional electrophysiology ablation procedures after the operation for right atrial flutter. The patients were treated successfully and were free of AF/atrial flutter/atrial tachycardia by long-term monitoring at 12 months. Despite the success of the cardioversion, ablation was classed as a failure in these patients because flutter and fibrillation are both considered as failures of the procedure. Reported limitations of this study are small sample size, the study included only patients with paroxysmal AF, and the results cannot be extrapolated to persistent or long-standing persistent AF in which substrate remodeling occurs. The study was not randomized to continuation of antiarrhythmic drugs, hence, the procedure's true efficacy cannot be determined with certainty. The benefit of this procedure compared with catheter ablation is also unknown.

Edgerton et al. (2009) performed a prospective study of bilateral mini-thoracotomies with video assistance. The procedure performed was bilateral pulmonary vein isolation with bipolar radiofrequency with documentation of conduction block, location of ganglionic plexi by high-frequency stimulation, and appropriate ablation and left atrial appendage exclusion/ excision. The study included 114 patients, 60 paroxysmal, 32 persistent, and 22 with long-standing persistent AF. The age at surgery, ejection fraction, and follow-up period were not different between groups. The patients had a history of long duration AF with 88.5% (10/113) reporting a history of more than one year and a further 6.2% (7/113) reporting 6–12 months of AF. Twenty-four (21.1%) had an unsuccessful previous catheter ablation. In 92.7% of the patients (101/109), the surgeon either amputated or sealed off the left atrial appendage. Definition of procedure success was regaining a normal sinus rhythm and able to discontinue any antiarrhythmic drugs. At six-month follow-up, with long-term monitoring, 52/60 (86.7%) patients with paroxysmal fibrillations were in normal sinus rhythm and 43/60 (71.7%) were both in normal sinus rhythm and off antiarrhythmic drugs. The patients with persistent AF had a lower success rate, with 18/32

(56.3%) being in normal sinus rhythm and 46.9% both in normal sinus rhythm and off antiarrhythmic drugs; for long-standing persistent cases, 11/22 (50%) were in normal sinus rhythm and 7/22 (31.9%) were also off antiarrhythmic drugs. There were 13 complications among the 114 patients; (11.4%) undergoing ablation. Two patients died within the 30-day perioperative period: one very early in the surgeon's experience from hemorrhage resulting from an avulsed left atrial appendage and one from unknown (inconclusive autopsy) cause. The author reports that further studies with longer-term monitoring are needed to firmly establish the safety of the procedure.

In a single center, prospective study, Han et al. (2009) describes the results of using a thorascopic approach and radiofrequency energy to perform bilateral pulmonary vein isolation and left atrial ganglionic plexi ablation for treatment of AF. The study included 45 patients; 33 with paroxysmal AF and 12 with persistent AF. Patient inclusion was symptomatic AF, failed at least one antiarrhythmic drug (AAD). Patients were presented with the option of (1) continued AAD trials (when additional AAD trials were an option), (2) percutaneous catheter radiofrequency ablation, or (3) minimally invasive surgical ablation. Thirteen patients were preferentially referred for minimally invasive surgical ablation based on clinical factors. Twelve patients (27%) had a prior unsuccessful catheter ablation for AF. Definition of procedure success was no atrial tachyarrhythmia of > 30 seconds' duration occurring > 90 days after surgery. One year success (defined as freedom from AF/atrial flutter/AT off AAD) of 65% (23 patients) is based on ECG and home monitoring data from 96% of our subjects regardless of the presence or absence of symptoms. At one year, 28 of 43 (65%) patients were in sinus rhythm off AAD with no AT > 30 seconds noted on office follow-up, on 30-day transtelephonic event monitor, or on pacemaker interrogation. Fifteen (35%) of the patients had atrial tachyarrhythmia recurrences by one year. Eight of 15 patients with recurrent AF had catheter ablation resulting in elimination and/or reduction of AF episodes in 7 of 8 patients. Four of 15 patients had AF elimination or reduction with antiarrhythmic drugs alone. Three patients did not benefit from surgery and received rate control only. There were no deaths; one phrenic nerve injury and two pleural effusions were the reported complications. Reported limitations by the author are that this study may be subject to referral bias based on a preference for surgery in patients with obesity, patients who could not tolerate or desired to discontinue warfarin, and patients who had abdominal or pelvic anatomy complicating catheter ablation. In addition, patients may have been biased in their decision to pursue surgical ablation when presented with the potential for repeat procedures after catheter ablation. This study was in a single center with limited numbers of patients which prevents drawing definitive conclusions.

In a multi-center observational study, Beyer et al. (2009) reported on the safety and efficacy of a thorascopic-assisted bilateral pulmonary vein isolation, autonomic denervation, and left atrial appendage resection via bilateral mini-thoracotomies for the treatment of AF. The study included 100 patients; paroxysmal AF in 39 patients, persistent AF in 29 patients, and permanent AF in 32 patients. Patient selection criteria included previously failed medical therapy or catheter ablation. Some referred patients were not considered suitable candidates if they had previous thoracic surgery leading to severe adhesions, had an enlarged left atrium (> 6.0 cm), had evidence of thrombus in the left atrium, were not able to tolerate single lung ventilation, or were considered too high risk because of age or comorbidities. Definition of procedure success was no AF or atrial flutter on follow-up electrocardiograms and Holter monitor recordings after the blanking period. Mean follow-up was 13.6 months. All patients had at least a 24-hour Holter monitor after a blanking period of three months and then on a recommended yearly basis. At follow-up, 87% of patients were in normal sinus rhythm (paroxysmal 93%, persistent 96%, permanent 71%; $p < 0.05$); antiarrhythmic therapy was discontinued in 62% of patients, and anticoagulation therapy was discontinued in 65% of patients. No intraoperative conversions and no mortality to report. Postoperative complications included pacemaker requirement in five patients (5%), phrenic nerve palsy in three patients (3%), hemothorax in three patients (3%), transient ischemic attack in one patient (1%), and pulmonary embolism in one patient (1%). The reported limitations of this study are that due to the study design, the results of these analyses may not be generalizable to all patients who have undergone this procedure at other centers. The follow-up, although complete, remains short. The long-term efficacy can only be known with additional follow-up. Furthermore, the use of at least a 24-hour Holter may be insufficient in the detection of recurrent tachyarrhythmias; perhaps the future availability of permanent loop recorders in this setting will allow to us to better ascertain the procedure's long-term success.

In a single center, study, Bagge et al. (2009) retrospectively studied 43 patients with symptomatic AF referred for thorascopic off-pump epicardial pulmonary vein isolation and ganglionated plexi ablation using radiofrequency energy. The study included 28 patients with paroxysmal AF, persistent AF (6), permanent AF (9) and lone AF (21). Patients who had failed at least one class I (86%) or III (93%) antiarrhythmic agent for symptomatic paroxysmal, persistent, or permanent AF were included in the study. Eighteen (42%) patients had

previously failed a transvenous endocardial pulmonary vein isolation, and 11 patients (26%) previously had an atrial flutter ablation. Six patients (14%) had a permanent pacemaker preoperatively. Definition of success of procedure was no documented symptomatic AF episodes or left atrial tachycardias after 12 months of follow-up, excluding the initial three months postoperatively, according to 12-lead ECG, 24-hour Holter recording, and spot ECG recorded when symptoms dictated. Overall, 25 of 33 patients (76%) followed up for 12 months had no symptomatic AF recurrences or AF episodes on 24-hour Holter recordings. The corresponding figures were 79% (19/24) for patients with paroxysmal AF, 100% (2/2) for persistent AF, and 57% (4/7) for permanent AF. The most common complication was bleeding events (9%) during pulmonary vein dissection. One patient was excluded because of premature termination of the procedure before pulmonary vein isolation due to bleeding from the right pulmonary vein during dissection. Major bleeding, defined as bleeding requiring transfusion or surgical intervention and/or leading to treatment cessation, occurred in six patients. One patient with permanent AF suffered from a stroke two days after the operation. Warfarin had been discontinued four days before the surgery but by mistake was not replaced by low-molecular-weight heparin until the day before operation. No patient developed pulmonary stenosis according to contrast tomography performed 5–12 months after surgery in 31 patients. The authors reported that divergent patient selections, variation in lesion sets used, and different study designs and follow-ups make it difficult to compare the present study with others.

Edgerton et al. (2008) reported on the efficacy of a minimally invasive surgical approach for the treatment AF that combines pulmonary vein antral isolation with targeted partial autonomic denervation. Seventy-four patients underwent video-assisted bilateral pulmonary vein antral isolation with confirmation of block and partial autonomic denervation with follow-up of six months or greater and a long-term rhythm monitor at six months. The study included 74 patients; 46 with paroxysmal AF, 14 with persistent AF and 14 with longstanding persistent AF. Thirteen patients had undergone one prior ablation, six had two prior ablations, and one patient had three prior ablations. Fifteen of the 74 had permanent pacemakers in place. Success was defined as no episodes > 15 seconds of AF on long-term monitoring. Treatment was successful in 83.7% of patients with paroxysmal AF and 56.5% of patients with persistent/long-standing persistent AF. Four patients suffered complications. There was one clotted hemothorax, which required thorascopic drainage. One patient had renal insufficiency without the need for dialysis, and one patient had transient brachial plexopathy, likely related to positioning on the operating table. There was one death related to tearing of the base of the left atrial appendage. Seven patients with paroxysmal AF were considered treatment failures by having episodes of AF of greater than 15 seconds. None of these patients became persistent after surgical ablation. Ten patients with persistent/long-standing persistent AF were considered treatment failures. Two of these patients were persistent after surgical ablation. The decision to discontinue antiarrhythmic drugs was not made until after the six-month office visit. The authors reported that this early data suggest this is a safe and efficacious approach for the treatment of paroxysmal AF but the technology is evolving.

Wudell et al. (2008) retrospectively studied 22 patients with symptomatic, intermittent AF who underwent video-assisted, thorascopic pulmonary vein isolation and left atrial appendage exclusion. All patients had either undergone unsuccessful antiarrhythmic drug therapy (21 of 22 patients), were intolerant of anticoagulants (6 of 22 patients), had a failed catheter-based ablation (7 of 22 patients), or had any combination thereof. Patients with greater than mild mitral regurgitation, severe systolic dysfunction, untreated coronary disease, morbid obesity, or significantly enlarged left atrium were, in general, not considered candidates for this procedure. Average follow-up time was 18.1 months. At one year, all underwent Holter monitoring at study end point. Definition of procedure success was no AF on ECG/end of study holter. At the end of follow-up, 20 patients (91%) were free of symptoms without antiarrhythmic therapy. Holter monitoring in these patients (performed more than six months after cessation of antiarrhythmic drugs) showed sinus rhythm and no AF. Twenty patients (91%) were no longer taking warfarin at the end of the study period. Major complications occurred in two patients: one had a pulmonary embolism and one had outpatient skin incision revision. One patient underwent right-sided catheter ablation for typical atrial flutter seven months after surgery. This study was in a single center with limited numbers of patients which prevents drawing definitive conclusions.

In a retrospective study, Sirak et al. (2008) studied 32 patients with persistent or longstanding persistent AF who underwent the totally thorascopic anti-arrhythmia procedure incorporating pulmonary vein isolation, mapping of epicardial autonomics, extended linear ablations across critical segments of atrial substrate, and ligation of the left atrial appendage. A total of 29 patients had persistent AF and three patients had long standing persistent AF. No patients had paroxysmal AF. Four patients had previously undergone at least one percutaneous left atrial ablation. Follow-up was six months with one week of continuous rhythm surveillance at 3, 6, and 13 months postoperatively. Definition of procedure success was no AF or atrial flutter lasting 30 seconds after an

initial 3-month blanking period. At six months, 20 of 24 patients (87.5 %) were in sinus rhythm; none of these 21 patients were on any anti-arrhythmic therapy, other than a low-dose beta-blocker. Five patients, including the three failures, underwent cardioversion within the first three months postoperatively. One patient underwent conversion to a median sternotomy due to an intraoperative retraction injury at the base of the left atrial appendage.

McClelland et al. (2007) prospectively evaluated 21 patients who had limited thoracotomy combining epicardial bipolar radiofrequency pulmonary vein antrum isolation and ganglionated plexus ablation. A total of 11 patients had paroxysmal AF, nine had persistent AF and one patient was excluded. Inclusion criteria were patients unresponsive to medical therapy, with failure of or intolerance to at least one class IC or Class III antiarrhythmic agent (generally two or more). Exclusion criteria included left atrium > 5.0 cm by transthoracic echocardiography, ejection fraction < 40%, inability to give informed consent, comorbid conditions with a life expectancy less than one year. Follow-up was one year (95%). Definition of procedure success was no AF/left atrial tachycardia and antiarrhythmic drug after 90-day blank period. Fifteen of 20 (75%) subjects overall, and 14 of 16 (87.5%) subjects with paroxysmal or persistent AF had a successful procedure. Two patients had right atrial flutter in follow-up; this was successfully ablated in both. One patient required transfusion for hemothorax related to the procedure. There were no other major complications. The reported limitations of this study are the lack of a comparison group and small sample size. The methods may not have been adequate to always clearly determine pulmonary vein isolation, the equipment and methods utilized to map ganglionated plexus differ between centers and the significance of these differences is unknown.

Pruitt et al. (2006) prospectively studied 50 drug-resistant, symptomatic AF patients who had thoracoscopic or robotic-assisted off-pump epicardial microwave ablation (MicroMaze procedure). The procedure was done thoracoscopically in 47 patients and robotic-assisted in three patients. Intermittent AF patients had pulmonary vein isolation whereas continuous patients had additional right and left atrial lesions performed. Forty-six patients (92.0%) had endoscopic stapling of the left atrial appendage. Thirty-three patients had intermittent AF and 17 had continuous AF. Twenty patients had prior cardioversion. Eleven patients had prior cardiac ablation. Mean duration of AF was 73.5 months. The definition of procedure success was not clearly defined. Thirty-five of 44 patients (79.5%) converted to normal sinus rhythm. Follow-up information was obtained through comprehensive questionnaires and telephone interview with patients, family members, or the patient's personal physician. Postoperative in-hospital complications were minimal with two patients (4.0%) experiencing diaphragmatic dysfunction. No patient required a permanent pacemaker implant. There was one late death (2.0%). In five patients (10.0%) the MicroMaze operation and subsequent electrophysiology intervention failed and a Cox-Maze III operation was performed. Several limitations of this study were reported such as lack of a comparison group, small sample size and brief duration of follow-up (mean, 7.5 months).

In a retrospective study, Jeanmart et al. (2006) studied the use of radiofrequency ablation to perform the mini-Maze procedure (pulmonary veins isolation). The aim of the study was to evaluate the authors' experience with the mini-Maze procedure, done with the use of the Cardioblade pen (Cardioblade™ Medtronic, Inc., Shoreview, MN), and minimally invasive mitral valve surgery. A total of 103 patients underwent a minimally invasive mitral valve surgery with concomitant pulmonary veins isolation (modified Maze procedure) performed with unipolar radiofrequency. A total of 41.2% were known to have intermittent AF and 58.8%, continuous AF; 67.7% of the patients were in AF at the time of surgery. Precise time of duration of AF was known in 47.6% (mean time, 30.3 +/- 28.9 months), but 47.7% were also known to have AF for many years. Mitral surgery included mitral valve repair in 71.8% and mitral valve replacement in 26.2%; 22 patients also received tricuspid annuloplasty. Major complications were mortality in 1%, myocardial infarction in 1%, stroke or transient ischemic attack in 1.9% and permanent pacemaker placement in 5.9%. At the time of discharge, 71.9% of patients were in SR, 21.9% in AF, 1% in atrial flutter, and 5.2% in paced rhythm. Seventy-six and a half percent of the patients left the hospital with an antiarrhythmic drug (amiodarone 56.9%, sotalol 15.7%). At the time of follow-up, 99 patients were still alive with a mean follow-up time of 17.4 +/- 14.1 months; 69.7% of patients were in SR, 28.3% in AF, and 2% were pacemaker-dependent. Patients received antiarrhythmic medication in 81.2% of cases (amiodarone 46.4%, sotalol 17.9%, beta-blocker 39.3%, digoxine 7.1%). Eleven new pacemakers were implanted (11.1%). The authors reported that further follow-up is necessary to assess the long-term efficacy of this approach and whether antiarrhythmic and anticoagulant medication could be discontinued.

Wolf et al. (2005) studied the safety of video-assisted thoracoscopic epicardial pulmonary vein isolation. Twenty-seven patients with AF (18 paroxysmal, four persistent, and five permanent) underwent bilateral video-assisted thoracoscopic off-pump epicardial pulmonary vein isolation and exclusion of the left atrial appendage. All

patients had unsuccessful drug therapy, were intolerant to antiarrhythmic drug therapy, or were intolerant to warfarin. The approach included two 10-mm ports and one 5-cm working port (non-rib spreading) bilaterally. Pulmonary vein isolation was achieved bilaterally by using a bipolar radiofrequency device. The left atrial appendage was excised with a surgical stapler. Bilateral pulmonary vein isolation and left atrial appendage excision was performed successfully in all patients. Average postoperative follow-up is approximately six months (173.6 days). Definition of procedure success was no AF on ECG or outpatient telemetry monitor. Twenty-three patients have been followed up for greater than three months, and 21 of these patients are free of AF (91.3%). Fifteen of the 23 patients evaluated beyond three months were successfully weaned from AADs, and six were weaned off AADs at their three-month visit. The results of magnetic resonance angiography were normal (no pulmonary vein stenosis) in 12 of 12 patients evaluated 3–6 months postoperatively. There were no conversions to sternotomy or thoracotomy. Postoperative complications in three patients were minor and resolved within 48 hours. One morbidly obese patient had more serious complications related to comorbid conditions. The authors report that continuing study evaluating the long-term safety and efficacy of this approach is indicated.

National Institute for Health and Clinical Excellence (NICE) (United Kingdom)

NICE Interventional Procedures Guidance issued in 2009 states, “There is evidence of efficacy for thoracoscopic epicardial radiofrequency ablation for atrial fibrillation in the short term and in small numbers of patients. The assessment of cardiac rhythm during follow-up varied between studies, and some patients were concomitantly treated with anti-arrhythmic medication. Evidence on safety shows a low incidence of serious complications but this is also based on a limited number of patients. Therefore the procedure should only be used with special arrangements for clinical governance, consent and audit or research” (NICE, 2009).

Professional Societies/Organizations

The American College of Cardiology (ACC)/American Heart Association (AHA)/European Society of Cardiology (ESC) 2011 focused update incorporated into the 2006 guidelines for the management of patients with atrial fibrillation states that if patients remain symptomatic with heart rate control and antiarrhythmic medication is either not tolerated or ineffective, then nonpharmacological therapies may be considered. These include left atrial ablation, the Maze operation, or atrioventricular nodal ablation and pacing. The guideline discusses that, despite its high success rate, the Maze operation has not been widely adopted other than for patients undergoing cardiac surgery because of the need for cardiopulmonary bypass. Many less invasive modifications are under investigation including thoracoscopic and catheter-based epicardial techniques. The guideline cites that if the efficacy of these adaptations approaches that of the endocardial Maze procedure, and they can be performed safely, they may become acceptable alternatives for a larger proportion of patients with AF (Wann, et al., 2011).

The International Society of Minimally Invasive Cardiothoracic Surgery (ISMICS) consensus statement for surgical ablation for atrial fibrillation (AF) in cardiac surgery addressed the following question, “In patients with AF undergoing cardiac surgery plus ablation, how do different ablative techniques compare with each other for conversion to sinus rhythm cut-and-sew, Cox Maze I, II, and III, pulmonary vein isolation, radiofrequency ablation, ultrasound ablation, laser ablation, and cryoablation?” The authors reported that they identified, “numerous studies (at least two randomized controlled trials (RCT), 51 non-RCTs) comparing two or more techniques or technologies for surgical ablation (bilateral versus left atrial [LA] lesions only, comparison between the following energy sources [cryothermal, radiofrequency {RA}, ultrasound, microwave and laser to the cut and sew technique; and comparison between different energy sources].) Because of heterogeneity in the techniques, technologies, and design bias of nonrandomized comparisons of prognostically disparate populations, it was not possible to aggregate data across studies to determine which factors were associated with greater success.” Furthermore, the authors reported that, “Although indirect comparisons may help to guide future research, it would be premature to declare one technique superior to another without adequately powered direct comparative analyses in randomized trials. Assessment of the results of the trials suggests that, at the least, there are no clear differences in conversion to sinus rhythm” (Ada, et al., 2010).

The Heart Rhythm Society (HRS)/European Heart Rhythm Association (EHRA)/European Cardiac Arrhythmia Society (ECAS) Consensus Statement on Catheter and Surgical Ablation of AF: Recommendations for Personnel, Policy, Procedures and Follow-up Report states the Maze procedure has had good long-term results in the treatment of both lone AF and AF associated with organic heart disease. The advent of ablation technology has simplified the surgical treatment of AF and expanded the indications, particularly for concomitant AF procedures in patients undergoing other cardiac surgery. Minimally invasive approaches presently in

development could expand the indications for stand-alone surgery AF in the future. The Task Force reports that, “Currently the limitations of the energy delivery devices and the attempt to deploy them through minimal access incisions or ports place constraints on the location and number of ablation lesions that can be performed. The impact of these alternative lesion patterns and the less invasive surgical approaches on results requires further observational prospective analysis.” It is the consensus of the Task Force that the following are appropriate indications for surgical ablation of AF:

- symptomatic AF patients undergoing other cardiac surgery
- selected asymptomatic AF patients undergoing cardiac surgery in whom the ablation can be performed with minimal risk
- stand-alone AF surgery should be considered for symptomatic AF patients who prefer a surgical approach, have failed one or more attempts at catheter ablation, or are not candidates for catheter ablation

Furthermore, the Task Force reports that, “the referral of patients for surgery with symptomatic, medically refractory AF in lieu of catheter ablation remains controversial. There have been no head-to-head comparisons of the outcomes of catheter and surgical ablation of AF. The decision-making in these instances needs to be based on each institution’s experience with catheter ablation and surgical ablation of AF, the relative outcomes and risks of each in the individual patient, and patient preference.” The Task Force has made recommendations for more consistency in measuring results from catheter ablation and surgical ablation, which should make future results from studies easier to compare. The Task Force reports that the term “Maze” procedure is appropriately used only to refer to the lesion set of the Cox-Maze III. Less extensive lesion sets should not be referred to as a “Maze” procedure. In general, surgical ablation procedures for AF can be grouped into three different groups: a full Cox-Maze procedure; left atria lesion sets, and pulmonary vein isolation (Calkins, et al., 2007). There have been no updates to this consensus statement since 2007.

The Workforce on Evidence Based Surgery of the Society of Thoracic Surgeons developed guidelines for reporting data and outcomes for the surgical treatment of AF (Shemin, et al., 2007). The report states that the complete Cox-Maze procedure is equally effective for patients with intermittent (paroxysmal or persistent) or continuous (permanent) AF; no other catheter or surgical procedure thus far developed can make that claim.

Summary

There is evidence from a number of prospective and retrospective studies that the surgical Maze procedure, performed during cardiopulmonary bypass with or without concomitant cardiac surgery, is safe and effective in restoring sinus rhythm (SR) in patients with medically refractory, intermittent (i.e., paroxysmal or persistent) or continuous (i.e., permanent), symptomatic AF in whom rhythm control is considered essential. In addition, there is some evidence that, when performed in conjunction with valve repair or replacement, the Maze procedure may reduce the risk of stroke, compared with valve replacement alone. Additional prospective studies are required to address issues, such as which lesioning technique is most effective and least invasive, and to further refine patient selection criteria.

Currently, there is insufficient evidence to support the use of minimally invasive, off-pump Maze procedures (e.g., pulmonary vein isolation via mini-thoracotomy) for the treatment of atrial fibrillation. Further well-designed randomized clinical trials are needed to determine the role of these procedures as an alternative to the gold standard surgical Maze procedure.

Coding/Billing Information

Note: This list of codes may not be all-inclusive.

Surgical Maze

Covered when medically necessary:

CPT®* Codes	Description
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33256	Operative tissue ablation and reconstruction of atria, extensive (eg, maze procedure); with 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 (List separately in addition to code for primary procedure)

ICD-9-CM Diagnosis Codes	Description
427.31	Atrial fibrillation

Minimally Invasive Off-pump Maze Procedure

Experimental/Investigational/Unproven/Not Covered:

CPT ^{®*} Codes	Description
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
33257	Operative tissue ablation and reconstruction of atria, performed at the time of other cardiac procedure(s), limited (eg, 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 (eg, maze procedure), without cardiopulmonary bypass (List separately in addition to code for primary procedure)
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, extensive (eg, maze procedure), without cardiopulmonary bypass

ICD-9-CM Diagnosis Codes	Description
427.0	Paroxysmal supraventricular tachycardia
427.31	Atrial fibrillation
427.32	Atrial flutter
	All other codes

***Current Procedural Terminology (CPT[®]) © 2010 American Medical Association: Chicago, IL.**

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Policy History

Pre-Merger Organizations	Last Review Date	Policy Number	Title
CIGNA HealthCare	6/15/2008	0094	Maze Procedure

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