



Cigna Medical Coverage Policy

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Subject **Maze Procedure**

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Coverage Policy

Cigna covers the surgical Maze procedure (Current Procedural Terminology [CPT®] codes 33256, 33259), 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 including a hybrid or convergent ablation procedure (CPT codes 33254, 33255, 33258, 33265, 33266) or a modified on-pump Maze procedure (CPT code 33257) for any indication including the treatment of atrial fibrillation because each 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 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 (Calkins, et al., 2012; Weimar, et al., 2011; Saltman, et al., 2009; Nussmeier, et al., 2009; 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 (Yanagawa, et al., 2013; Ad, et al., 2013; Albage, et al., 2013; Saint, et al., 2013; Melby, et al., 2013; Okada, et al., 2013; Kong, et al., 2010; VonOppell, et al., 2009; Lee, et al., 2009; Albrecht, et al., 2009; Wang, et al., 2009; Louagie, et al., 2009; Lönnerholm, et al., 2008; Srivastava, et al., 2008; Khargi, et al., 2007; Doty, et al., 2007; Stulak, et al., 2007a; Stulak, et al., 2007b; Wong, et al., 2006; Gillinov, et al., 2006; Melby, et al., 2006; Gaynor, et al., 2005; Reston and Shuhaiber, 2005; Khargi, et al., 2005; Bando, et al., 2002; Cox, et al., 2000).

In 2013, the Agency for Healthcare Research and Quality (AHRQ) published a comparative effectiveness review of treatment of atrial fibrillation. The key point under procedural therapies states "Based on seven RCTs (one good, six fair quality) involving 361 patients, surgical Maze at the time of other cardiac surgery (specifically mitral valve surgery) is superior to mitral valve surgery alone for maintenance of sinus rhythm over at least 12 months of follow-up in patients with persistent AF" (AHRQ, 2013).

Minimally Invasive Maze Procedures

Despite its high success rate, the surgical 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 off-pump Maze procedures including hybrid or convergent ablation procedures are being investigated to treat atrial fibrillation (AF). Examples of minimally invasive, off-pump surgical techniques include the thoracoscopic Wolf MiniMaze™ procedure and the Ex-Maze which uses a paracardioscopy approach. A simultaneous endocardial and epicardial closed chest hybrid ablation procedure, the convergent procedure, is being investigated.

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 long standing persistent AF, sometimes referred to as chronic or permanent AF. A new version of the mini Maze procedure is the total thoracoscopic 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. The long-term efficacy of “mini-maze” procedures is lower than that of the Maze procedure, but because of their ease and low risk, their use has become widespread (Morady, et al., 2011; Nussmeier, et al., 2009; Cheema, et al., 2009; Gillinov, 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; 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).

A hybrid approach with extensive periprocedural electrophysiological testing during thoracoscopic pulmonary vein antrum isolation, left atrial ablation lines, and ganglionated plexus (GP) ablation has been studied. It is suggested that electrophysiological guided thorough pulmonary vein isolation and additional left atrial lines creation presumably contribute in achieving a high success rate in the surgical epicardial approach in treatment of AF (Robertson, et al., 2013; Krul, et al., 2011).

A closed chest hybrid procedure known as the convergent procedure is being investigated for the treatment of chronic or persistent AF. The convergent procedure was developed to replace standard catheter ablation. The convergent procedure combines minimally invasive surgery and catheter ablation. During the convergent procedure, the cardiac surgeon and the electrophysiologist collaborate to identify the source of AF and create a pattern of scar on the heart. The entire procedure is performed with miniature cameras and instruments and with small catheters and electrodes in a special hybrid electrophysiology/operating room suite outside of the operating room. Pericardioscopy provides endoscopic access to and visualization of the beating epicardial surface via the central tendon of the diaphragm without the need for cardiopulmonary bypass or chest incisions. The convergent procedure is the simultaneous creation of the surgeon's epicardial ablation pattern and the electrophysiologist's endocardial ablation pattern. The surgeon's ability to effectively create robust and visible epicardial ablation lines greatly reduces the amount of endocardial tissue which must be ablated to complete a comprehensive and bi-atrial pattern. The convergent pattern includes pulmonary vein isolation; coronary sinus ablation; mitral annulus ablation; posterior left atrial ablation; and ablation of the cavotricuspid isthmus. Because data from recent studies are still incomplete, it has not been established whether the single or staged approach will result in favorable outcomes (Edgerton and Edgerton, 2012; Edgerton, et al., 2010; Kiser, et al., 2011). There is insufficient evidence in the peer-reviewed medical literature to indicate the safety, efficacy and long-term outcomes with the convergent procedure.

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 including hybrid or convergent ablation procedures. 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 (LaMeir, et al., 2013a; Gehi, et al., 2013; Gersak, et al., 2012; LaMeir, et al., 2012; Zembela, et al., 2012; Pison, et al., 2012; Boersma, et al., 2012; Santini, et al., 2012; Kasirajan, et al., 2012; Kiser, et al., 2011; Krul, et al., 2011; LaMeir, et al., 2011; Wang, et al., 2011; Mahapatra, et al., 2011; Nasso, et al., 2011; Speziale, et al., 2010; Edgerton, et al., 2009, 2010; Kiser, et al., 2010; Wudell, et al., 2008; Sirak, et al., 2008; McClelland, et al., 2007; Pruitt, et al., 2006; Jeanmart, et al., 2006; Wolf, et al., 2005).

Boersma et al (2012) reported the first randomized clinical trial comparing the efficacy and safety of catheter ablation (CA) and minimally invasive surgical ablation (SA) during a 12-month follow-up. A total of 124 patients with antiarrhythmic drug–refractory atrial fibrillation with left atrial dilatation and hypertension (42 patients, 33%) or failed prior CA (82 patients, 67%) were randomized to CA (63 patients) or SA (61 patients). CA consisted of linear antral pulmonary vein isolation and optional additional lines. SA consisted of bipolar radiofrequency isolation of the bilateral pulmonary vein, ganglionated plexi ablation, and left atrial appendage excision with optional additional lines. Follow-up at six and 12 months was performed by ECG and 7-day Holter recording. The primary end point, freedom from left atrial arrhythmia > 30 seconds without antiarrhythmic drugs after 12 months, was 36.5% for CA and 65.6% for SA ($p=0.0022$). There was no difference in effect for subgroups, which was consistent at both sites. The primary safety end point of significant adverse events during the 12-month follow-up was significantly higher for SA than for CA ($n=21$ [34.4%] versus $n=10$ [15.9%]; $p=0.027$), driven mainly by procedural complications such as pneumothorax, major bleeding, and the need for pacemaker. In the CA group, one patient died at 1 month of subarachnoid hemorrhage. Reported limitations of this study arrhythmia follow-up was performed with intermittent ECG, 7-day Holter, and sometimes event recording, which may underestimate absolute arrhythmia recurrence. Most patients in the study had undergone a prior unsuccessful CA as inclusion criterion. This may make the conclusion less applicable to patients with the inclusion criterion of dilated LA or to the general AF population. In the population studied, 67% had paroxysmal AF and 33% had continuous persistent AF <1 year. Although the authors did not observe a significant effect of AF type on efficacy, the study may have been underpowered for this factor. In the patients who had AF during

the CA or SA procedure, PV ablation was simply repeated without prior measurement of actual PV-LA conduction. In both the CA and SA groups, there were differences between the sites in several of the practical procedural details. Although the efficacy of CA and SA was consistent and similar at the sites, the trial was not powered to study the effect of such differences.

Systematic Review/Meta-Analysis: In a systematic literature overview and analysis, Krul et al. (2013, 2011) reported on the first results and progress made with minimally-invasive surgery using radiofrequency energy in the treatment of atrial fibrillation (AF). The minimally invasive treatment for AF tries to combine the success rate of surgical treatment with a less invasive approach to surgery. A total of 23 studies were included. All studies were observational in nature and 18/23 studies were performed in a single center. In all but two studies bilateral thoracotomy or thoroscopic approach to surgery was performed, two groups used a monolateral thoracotomy. Two studies performed a hybrid procedure; one study performed extensive electrophysiological measurements epicardially and one group performed simultaneous transvenous catheter measurements. There were differences in the execution of the minimally-invasive surgical procedure. In 15 studies ganglion plexus (GPs) around the pulmonary veins were ablated. In four studies additional left atrial ablation lines (ALAL) were performed. Single procedure success rate was 69% (without antiarrhythmic drugs (AAD) and 79% with AAD at one year follow-up. Mortality was 0.4% and various complications were reported (3.2% surgical, 3.2% post-surgical, 2.6% cardiac, 2.1% pulmonary, 1.7% other). The authors reported that the success rates of minimally-invasive surgery for are similar to the success rates between that of the standard maze procedure and catheter ablation however, minimally-invasive surgery is still evolving, for instance by the recent inclusion of electrophysiological endpoints.

In a systematic literature overview and analysis, LaMeir et al. (2013b) reported on minimally invasive surgery (MIS) for the treatment of stand alone-atrial fibrillation (SA-AF). Twenty-eight studies were included; 27 were observational in nature and one study was prospective non-randomized (n=1051). The authors reported that suboptimal results were obtained when employing microwave and high focused ultrasound energies. In contrast, MIS ablation of SA-AF achieved satisfactory one-year results when the bipolar radiofrequency was employed as energy source, with antiarrhythmic drug-free success rate comparable to percutaneous catheter ablation (PCA). The success rate in paroxysmal was even higher than in PCA. In contrast, ganglionated plexi ablation and left atrial appendage removal seem not to influence the recurrence of AF and the occurrence of postoperative thromboembolic events. The authors reported that a high complication rate suggests that such techniques require further refinement. Overall, early complications occurred in 125 patients and the complication rate ranged from 0% to 39%. Early complications were as follows: 12 conversions to sternotomy, 15 bleedings, 10 access-port complications, 11 cardiac complications, 8 cerebrovascular events, and 28 pulmonary complications. Furthermore, 38 other complications occurred: four renal insufficiencies, 16 diaphragmatic-phrenic nerve dysfunctions, one liver damage, and four brachial plexopathies were observed. Finally, 10 patients required a pacemaker implantation and two patients underwent PCA within 30 days. The authors reported that the preliminary results of the hybrid approach are promising but they need to be confirmed. Demonstration of the effectiveness and safety of the hybrid approach awaits the completion of studies that are in progress.

Professional Societies/Organizations

In 2014, the American College of Cardiology (ACC)/American Heart Association (AHA) and Heart Rhythm Society (HRS) published an updated guideline which supersede the 2011 focused updates and the 2006 guidelines for the management of patients with atrial fibrillation (January, et al., 2014).

Guideline recommendations are classified as Class I, Class IIa, Class IIb, and Class III. The classification system is described as follows:

- Class I: Benefit >>>Risk; Procedure/Treatment should be performed/administered.
- Class IIa: Benefit >> Risk; Additional studies with focused objectives needed. It is reasonable to perform procedure/administer treatment.
- Class IIb: Benefit ≥ Risk; Additional studies with broad objectives needed; additional registry data would be helpful. Procedure/treatment may be considered.
- Class III: Risk ≥ Benefit; Procedure/treatment should not be performed/administered, since it is not helpful and may be harmful.

The weight of evidence supporting each recommendation is classified as follows:

- Level A: Multiple populations evaluated. Data derived from multiple randomized clinical trials or meta-analyses.
- Level B: Limited populations evaluated. Data derived from a single randomized trial or nonrandomized studies.
- Level C: Very limited populations evaluated. Only consensus opinion of experts, case studies, or standard of care.

The following recommendations for surgical maze procedures are included in the 2014 guideline:

Class IIa

- An AF surgical ablation procedure is reasonable for selected patients with AF undergoing cardiac surgery for other indications. (Level of Evidence: C)

Class IIb

- A stand-alone AF surgical ablation procedure may be reasonable for selected patients with highly symptomatic AF not well managed with other approaches. (Level of Evidence: B)

The 2012 updated consensus statement on catheter ablation and surgical ablation of atrial fibrillation from the Heart Rhythm Society reported 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 and randomized trials” (Calkins, et al., 2012).

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.

Use Outside of the US

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” (Ad, et al., 2010).

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 or modified on-or off-pump Maze procedures, including hybrid or convergent ablation procedures, 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 or to catheter-based ablation.

Coding/Billing Information

Note: 1) This list of codes may not be all-inclusive.

2) Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement.

Surgical Maze

Covered when medically necessary:

CPT®* Codes	Description
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)

Minimally Invasive On-pump Maze Procedure

Experimental/Investigational/Unproven/Not Covered:

CPT®* Codes	Description
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)

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
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

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