Maze Procedure

Number: 0225

POLICY

*Please see amendment for Pennsylvania Medicaid at the end of this CPB.

Aetna considers the Maze procedure, performed with cardiopulmonary bypass on a beating heart, medically necessary for members with atrial fibrillation/flutter when any of the following criteria is met:

- Member cannot tolerate the side effects of drug therapy (adequate documentation of the nature and extent of the intolerance is required); or
- Member is suffering the hemodynamic consequences of chronic atrial fibrillation/flutter despite adequate attempts at medical management; or
- Member is at high-risk for thromboembolism as evidenced by either:
  - A previous episode of thromboembolism when other sources of emboli have been ruled out, or
  - Documented long-standing atrial fibrillation in members with mitral valve disease undergoing open surgical repair of the mitral valve.
Aetna considers the Maze procedure experimental and investigational for all other indications because its effectiveness for indications other than the ones listed above has not been established.

Aetna considers minimally invasive, off-pump Maze procedures (including the hybrid Maze and the Convergent hybrid procedure), also known as thoracoscopic off-pump surgical ablation (TOPS), experimental and investigational for atrial fibrillation or flutter because there is insufficient evidence of their effectiveness.

Aetna considers concomitant Maze and septal myectomy medically necessary for the treatment of hypertrophic obstructive cardiomyopathy plus refractory atrial fibrillation/flutter.

See also CPB 0019 - Holter Monitors (/../1_99/0019.html).

BACKGROUND

The Maze procedure is a surgical treatment of atrial fibrillation (AF) in which multiple atrial incisions interrupt the pathogenic reentrant circuits and also direct the sinus impulses to the AV node along a specified route. In addition, multiple blind "alleys" off the main conduction route allow for activation of the entire atrium. By eliminating AF, this technique not only addresses the hemodynamic consequences of AF, it also eliminates the threat of thromboembolism AF can cause.

As part of the ongoing study of this procedure, individuals typically undergo a variety of post-operative tests to evaluate the status of the atria. Unless clinically indicated by the member's signs and symptoms, these tests are considered not routinely medically necessary for post-operative evaluation. Such tests include: endocardial catheter electrophysiology study; 24-hour Holter monitor; exercise stress test; and color-flow Doppler evaluation of transmitral and transtricuspid valve flow.

Gaynor and co-workers (2005) stated that the Cox maze procedure remains the gold standard for the treatment of AF and has excellent long-term efficacy. The most significant predictor of late recurrence was
duration of pre-operative AF, suggesting that earlier surgical intervention would further increase effectiveness. This is in agreement with the findings of Chen et al (2005) who noted that the pre-operative left atrial size and duration of AF are primary predictors of sinus conversion by the radiofrequency Maze procedure for patients with persistent AF and mitral valve disease. Moreover, in a systematic review on surgical treatment of AF, Khargi et al (2005) could not identify any significant difference in the post-operative sinus rhythm conversion rates between the classical "cut and sew" Cox-Maze III technique and the alternative sources of energy (e.g., radiofrequency-microwave and cryoblation), which were used to treat AF.

Thorascopic off-pump (TOP) surgical ablation (also known as mini Maze procedure, absent thoracotomy Maze procedure) is performed on a "beating heart" – the heart is not arrested via bypass. Use of a thoroscope (a video telescope) helps surgeons guide the energy source to the atria. Radiofrequency energy applied to the outside of the heart (epicardial ablation) is used for lesion creation. This approach has many variants, but commonly involves pulmonary vein isolation at a minimum, as well as other potential ablation lines. Bipolar radiofrequency energy is typically employed, in contrast to the unipolar energy employed in catheter ablation.

Krul et al (2013) presented a systematic literature overview and analysis of the first results and progress made with minimally-invasive surgery using radiofrequency energy in the treatment of AF. The minimally-invasive treatment for AF tries to combine the success rate of surgical treatment with a less invasive approach to surgery. It has the additional potential advantage of ganglion plexus (GP) ablation and left atrial appendage exclusion. Furthermore, additional left atrial ablation lines (ALAL) can be created in non-paroxysmal AF patients. For the search query, multiple databases were used. Exclusion and inclusion criteria were applied to select the publications to be screened. All remaining articles were critically appraised and only relevant and valid articles were included in the results. A total of 23 studies were included. In 15 studies GPs around the pulmonary veins were ablated. In 4 studies ALAL were performed. Single procedure success rate was 69 % (95 % confidence interval [CI]: 58 % to 78 %) without anti-arrhythmic drugs (AAD) and 79 % (95 % CI: 71 % to 85 %) with AAD at 1 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, and 1.7 % other). The authors concluded that the 23 studies of minimally-invasive surgery for AF have been reviewed with success rates between that of the standard maze procedure and catheter ablation. These first combined results show promise; however, minimally-invasive surgery is still evolving, for instance by the recent inclusion of electrophysiological endpoints. Furthermore, the type of ALAL and the additional value of GP ablation have to be elucidated.

Sunderland et al (2011) examined if left atrial size reduction compared to maze surgery alone improve maze surgery success in adults undergoing a maze procedure for AF. A total of 58 papers were found using the reported search, of which 8 represented the best evidence to answer the clinical question. The authors, journal, date and country of publication, patient group studied, study type, relevant outcomes and results of these papers were tabulated. Four out of 8 papers compared a volume reduction technique as an adjunct to the maze procedure to a maze procedure alone – all 4 papers reported that atrial volume reduction significantly increased restoration of sinus rhythm: 89.3 % versus 67.2 %, p < 0.001; 85 % versus 68 %, p < 0.05; 84 % versus 68 %, p < 0.05; 90 % versus 69 %, p < 0.05. Three out of 8 papers had no control group but reported good rates of sinus rhythm restoration at last follow-up – 90 %, 92 % and 89 %, respectively – despite the study population including atrial enlargement, a risk factor for failure of a maze procedure. One paper reported no benefit of an atrial reduction plasty in patients with a left atrium (LA) greater than 70 mm. An enlarged LA is a risk factor for failure of a maze procedure, and various models of AF suggested that reducing atrial mass and/or diameter may help to abolish the re-entry circuits underlying AF. Furthermore, AF is uncommon when left atrial diameter is less than 40 mm, so there is at least some physiological basis for atrial reduction surgery in aiding the success of a maze procedure. The evidence suggested that patients with an enlarged (greater than or equal to 55 mm) or giant (greater than or equal to 75 mm) LA who are at risk of failing to obtain sinus conversion after a standard maze procedure may derive benefit from concomitant atrial reduction surgery using either a tissue excision or a tissue plication technique. However, the authors concluded that the evidence is not strong since the papers available are
not readily comparable owing to substantial variations in the populations and procedures involved. They, therefore, emphasized the need for prospective, randomized studies in this area.

Bum Kim et al (2012) noted that the long-term benefits of the maze procedure in patients with chronic AF undergoing mechanical valve replacement who already require lifelong anti-coagulation remain unclear. These investigators evaluated adverse outcomes (death; thromboembolic events; composite of death, heart failure, or valve-related complications) in 569 patients with AF-associated valvular heart disease who underwent mechanical valve replacement with (n = 317) or without (n = 252) a concomitant maze procedure between 1999 and 2010. After adjustment for differences in baseline risk profiles, patients who had undergone the maze procedure were at similar risks of death (hazard ratio, 1.15; 95% CI: 0.65 to 2.03; p = 0.63) and the composite outcomes (hazard ratio, 0.82; 95% CI: 0.50 to 1.34; p = 0.42) but a significantly lower risk of thromboembolic events (hazard ratio, 0.29; 95% CI: 0.12 to 0.73; p = 0.008) compared with those who underwent valve replacement alone at a median follow-up of 63.6 months (range of 0.2 to 149.9 months). The effect of superior event-free survival by the concomitant maze procedure was notable in a low-risk EuroSCORE (0 to 3) subgroup (p = 0.049), but it was insignificant in a high-risk EuroSCORE (greater than or equal to 4) subgroup (p = 0.65). Furthermore, the combination of the maze procedure resulted in superior left ventricular (p < 0.001) and tricuspid valvular functions (p < 0.001) compared with valve replacement alone on echocardiographic assessments performed at a median of 52.7 months (range of 6.0 to 146.8 months) after surgery. The authors concluded that compared with valve replacement alone, the addition of the maze procedure was associated with a reduction in thromboembolic complications and improvements in hemodynamic performance in patients undergoing mechanical valve replacement, particularly in those with low-risk of surgery.

With thorascopic “off-pump” (TOP) surgical ablation, the heart is not arrested via bypass, and minimally-invasive techniques are used. Radiofrequency energy applied to the outside of the heart (epicardial ablation) is used for lesion creation. This approach has many variants, but typically involves pulmonary vein isolation at a minimum, as well as other potential ablation lines. An assessment by the Institute for Clinical and
Economic Review (2010) found that the evidence for TOP surgical ablation was particularly scant; the ICER review identified no randomized controlled trials, and the remaining case series and cohort studies varied significantly in technical approach, outcome measurement, and level of reporting detail. The ICER review stated: "Thorascopic, off-pump surgical ablation is an emerging surgical technique, as there are many variations in how the procedure is performed, there is no evidence on longer term outcomes, and what evidence is available on intermediate or surrogate outcomes is limited to a few surgical case series."

La Meir et al (2013) stated that despite its proven effectiveness, the Cox-Maze III procedure did not gain widespread acceptance for the treatment of stand-alone AF (SA-AF) because of its complexity and technical difficulty. Surgical ablation for SA-AF can now be successfully performed utilizing minimally invasive surgery (MIS). These investigators provided an overview of state-of-the-art MIS for the treatment of SA-AF. Studies selected for this review were identified on PubMed and exclusion and inclusion criteria were applied to select the publication to be screened. A total of 28 studies were included; 27 (96.4 %) were observational in nature whereas 1 was prospective non-randomized. The total number of patients was 1,051 (range of 14 to 114). Mean age ranged from 45.3 to 67.1 years. Suboptimal results were obtained when employing microwave and high focused ultrasound energies. In contrast, MIS ablation of SA-AF achieved satisfactory 1-year results when the bipolar radiofrequency was employed as energy source, with anti-arrhythmic drug-free success rate comparable to percutaneous catheter ablation (PCA). The success rate in paroxysmal was even higher than in PCA. In contrast, ganglionic plexi ablation and left atrial appendage removal seem not to influence the recurrence of AF and the occurrence of post-operative thrombo-embolic events. The authors concluded that minimally invasive surgery ablation of SA-AF achieved satisfactory 1-year results when the bipolar radiofrequency was employed. Nevertheless, the relatively high complication rate reported suggested that such techniques require further refinement. Finally, the authors noted that preliminary results of the hybrid approach are promising but they need to be confirmed.
Ismail et al (2014) presented a novel way to perform the mini-maze procedure through the left atrial appendage. By this way, the usual additional incision of the intra-atrial groove is avoided, especially in patients receiving coronary artery bypass grafting (CABG) or aortic valve replacement without mitral valve disease. These investigators retrospectively analyzed 23 consecutive patients who received this novel mini-maze procedure between 2009 and 2011. In recognition of a learning curve, the authors divided the patients into 2 groups (Group 1: Patients 1 to 11 versus Group 2: Patients 12 to 23), according to the date of operation. In Group 2, 7 patients (58.33 %) were completely free of atrial fibrillation at the time of the follow-up. In Group 1, only 2 (18.18 %) patients were successfully treated resulting in a stable sinus rhythm at the time of the follow-up. The authors concluded that the mini-maze procedure performed through the left atrial appendage is a safe and feasible technique; however, it seems to be less effective than the Cox-maze III procedure and is associated with a learning curve.

Also an UpToDate review on "Surgical approaches to prevent recurrent atrial fibrillation" (Cheng, 2014) states that "The FAST trial randomly assigned 124 patients with antiarrhythmic drug-refractory atrial fibrillation (AF) with left atrial dilatation and hypertension (33 percent) or failed prior RCA [catheter based pulmonary vein radiofrequency ablation] (67 percent) to either minimally invasive surgical ablation or RCA. At 12 months, the primary end point of freedom from left atrial arrhythmia of greater than 30 seconds without antiarrhythmic drugs was significantly higher in the surgical ablation group (65.6 versus 36.5 percent). However, there were significantly more periprocedural complications such as pneumothorax, major bleeding, and the need for pacemaker in the surgical ablation group (35.4 versus 15.9 percent)".

Pinho-Gomes et al (2014) noted that the first Cox-maze procedure was performed in 1987, demonstrating the feasibility of a non-pharmacological treatment for AF. Since then, surgery for AF has changed over time, in parallel with technological advances. Replacement of surgical incisions with linear ablation lines made a previously cumbersome procedure accessible to most surgeons, without compromising success. On the other hand, new ablation technologies paved the way for the development of minimally invasive surgery, which may potentially extend the scope of surgery to patients who would otherwise be deemed unsuitable.
Nonetheless, literature on minimally invasive surgery is still scarce and randomized clinical trials currently under way are expected to shed light on some controversial issues. Moreover, successful AF treatment will probably rely on close collaboration between surgery and electrophysiology. Indeed, the hybrid procedure, though still in its very beginning, seems to combine the best of catheter and surgical ablation. However, further studies are warranted to determine the effectiveness of this promising strategy, especially in patients with persistent and longstanding persistent AF.

Lawrance et al (2015) reviewed the indications, evolution of technique, and results of surgical ablation for AF. With the introduction of the Cox-Maze IV procedure utilizing bipolar radiofrequency ablation and cryoablation, long-term studies have demonstrated a significant decrease in aortic cross-clamp times and major complications with a comparable rate of restoration of sinus rhythm. New hybrid approaches utilizing both catheter-based ablation and minimally invasive surgical approaches have been developed, but have not been standardized. Early studies have demonstrated reasonable success rates of hybrid procedures, with advantages that include confirmation of conduction block, decreased surgical morbidity, and possibly reduced morbidity. However, hybrid approaches have the disadvantage of significantly increased operative times. The authors concluded that the Cox-Maze IV is currently the gold standard for surgical treatment of AF. New hybrid approaches have potential advantages with promising early results, but a standard lesion set, improvement in operative times, and long-term results still need to be evaluated.

Furthermore, an UpToDate review on "Surgical approaches to prevent recurrent atrial fibrillation" (Cheng, 2014) states that "Surgical approaches that are available include the maze and corridor operations as well as radiofrequency or cryoablation. These procedures appear effective in a high percentage of patients. However, the follow-up for many of these studies was limited in scope and did not employ very rigorous arrhythmia surveillance". It does not mention hybrid or convergent maze as a therapeutic option.

A review by Je and colleagues (2015) noted that there is a growing trend to perform off-bypass surgical ablation for AF because it is perceived to
be safer and more effective than the Cox-Maze procedure with cardio-pulmonary bypass (CPB) support. These investigators compared 3 minimally invasive stand-alone surgical ablation procedures for AF: (i) the endocardial Cox-Maze procedure, (ii) epicardial surgical ablation and (iii) a hybrid epicardial surgical and catheter-based endocardial ablation procedure (hybrid procedure). Relevant studies were identified in MEDLINE and the Cochrane Database of Systematic Reviews according to the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidelines. From 565 initial studies, 37 were included in this review. The total number of patients across all studies was 1,877 (range of 10 to 139). Two studies reported on endocardial Cox-Maze procedures (n = 145), 26 reported on epicardial surgical ablation (n = 1,382) and 9 reported on hybrid surgical ablation (n = 350). For minimally invasive Cox-Maze, epicardial and hybrid groups, operative mortality rates were 0, 0.5 and 0.9 %, peri-operative permanent pacemaker insertion rates were 3.5, 2.7 and 1.5 %, incidence of conversion to median sternotomy was 0, 2.4 and 2.5 %, and re-operation for bleeding was 1.0, 1.5 and 2.2 %, with mean length of stay (days) of 5.4, 6.0 and 4.6, respectively. At 12 months, rates of sinus rhythm restoration were 93, 80 and 70 %, and sinus restoration without anti-arrhythmic medications was 87, 72 and 71 %, for Cox-Maze, epicardial and hybrid procedures, respectively. The authors concluded that of the 3 procedures, the minimally invasive Cox-Maze procedure with CPB support was most effective for the treatment of stand-alone AF and had important safety advantages in conversion to sternotomy and major bleeding. They stated that the minimally invasive Cox-Maze procedure with CPB support also demonstrated the potential for a higher success rate 12 months following the procedure.

Moslemi et al (2016) stated that a complete Cox maze IV procedure is difficult to accomplish using current endoscopic and minimally invasive techniques. These techniques are hampered by inability to adequately dissect the posterior structures of the heart and place all necessary lesions. These investigators presented a novel approach (a hybrid mini-Maze procedure), using robotic technology, that achieves placement of all the lesions of the complete maze procedure. In 3 cadaveric human models, the technical feasibility of using robotic instruments through the right chest to dissect the posterior structures of the heart and place all
Cox maze lesions was performed. The entire posterior aspect of the heart was dissected in the cadaveric model facilitating successful placement of all Cox maze IV lesions with robotic assistance through minimally invasive incisions. The authors concluded that the robotic Cox maze IV procedure through the novel right thoracic approach is feasible. This obviated the need for sternotomy and avoided the associated morbidity of the conventional Cox-maze procedure.

In a retrospective, cohort study, Horn and colleagues (2016) identified clinical factors associated with metabolic acidosis following the Mini-Maze procedure. After Institutional Review Board (IRB) approval, these investigators studied patients undergoing the Mini-Maze procedure, off-pump CABG or patients conventional Cox-Maze on cardiopulmonary bypass. The first base deficit value obtained in the Intensive Care Unit (ICU) was used as a measure of metabolic acidosis. Using logistic regression with Akaike information criteria, these researchers analyzed pre-operative, intra-operative, and post-operative data to determine the factors associated with changes in base deficit. A multi-variable model using step-wise selection demonstrated that diabetes mellitus and weight were associated with a decrease in the base deficit by 2.87 mEq/L (95 % CI: -5.55 to -0.19) and 0.04 mEq/L (95 % CI: -0.08 to 0.004), respectively. Furthermore, creatinine was associated with a 1.57 mEq/L (95 % CI: 0.14 to 2.99) increase in the base deficit. The authors concluded that the Mini-Maze procedure was not associated with post-operative metabolic acidosis. Instead, non-diabetic patients and patients with higher creatinine were associated with greater base deficits after undergoing cardiac surgery. This study had several drawbacks: (i) these researchers only measured base deficit and not the type of acid accumulating, they were limited in not being able to discriminate between lacto- and keto-acidosis. Further study is needed to ascertain the types and amounts of acids produced; (ii) there was a sex imbalance between the groups, with the Mini-Maze group including the least women. However, these investigators adjusted for this in their multivariable analyses; (iii) with only 36 subjects in 3 groups; the authors were at increased risk of both Type I error, in accepting diabetes as associated with the base deficit, and Type II error, in rejecting Mini-Maze as associated with the base deficit. However, the Mini-Maze is still a relatively novel and uncommon operation. As the operation becomes
more common, future studies with larger populations will be possible; and (iv) the study was conducted in only 1 center and may not generalize to centers that perform these operations with different techniques or different anesthetics.

An UpToDate review on "Surgical ablation to prevent recurrent atrial fibrillation" (Lee, 2016) stated that "Minimally invasive approach – While the Maze procedure is usually performed at the time of cardiac surgery using a sternotomy, it has also been performed through a thoracotomy with a minimally invasive approach to mitral valves. However, there are limited data available on the efficacy of using this approach".

Itaya and colleagues (2018) noted that left atrial appendage aneurysm (LAAA) is a rare congenital heart anomaly that frequently becomes apparent after middle age. These investigators reported a case of LAAA in a 63-year old woman with stroke. After stabilization of ischemic cerebral stroke, the patient underwent left atrial appendectomy with full Maze procedure and tricuspid annuloplasty under cardiac arrest with cardio-pulmonary bypass. The patient has been living a healthy life without anti-coagulants post-operatively. The authors concluded that resection and the full Maze procedure is a durable and effective procedure for LAAA with chronic AF. These preliminary findings need to be validated by well-designed studies.

Hybrid Maze Procedure

Geney and colleagues (2017) noted that AF is the most common cardiac arrhythmia in the U.S. It has been associated with a reduction in patient quality of life (QOL) and more serious complications such as stroke and heart failure (HF). In a retrospective, chart-review study, these researchers compared the efficacy of commonly performed invasive procedures in keeping patients in normal sinus rhythm. This trial was carried out on all patients who underwent primary radiofrequency (RF) catheter ablation, the complete Cox-Maze, or the hybrid Maze at OSF Saint Anthony Medical Center between January 2010 and December 2013 (n = 140). Immediately post-procedure, arrhythmia recurrence rates did not differ between the groups (p = 0.28). At all follow-up points thereafter, however, differences in procedural efficacy between surgical and catheter therapy remained highly significant (p < 0.001). At 2 years,
20.3 % of the catheter ablation patients were in normal sinus rhythm, when compared to 57.9 % of hybrid Maze and 72.7 % the complete Cox-maze groups. A difference in major complication rates was noted ($p = 0.04$), with the complete Cox-Maze having a 17.4 %, the hybrid Maze having 22.7 %, and the catheter ablation group having 5.6 %. The authors concluded that this study was unable to detect differences in the efficacy rates of the surgical procedures, however they were both superior to catheter ablation. Although the hybrid approach was considered minimally invasive, complication rates were similar to those of the complete Cox-Maze. These researchers stated that catheter ablation was the safest procedure, and since, at this time, evidence of any long-term survival advantage after the use of aggressive rhythm therapy is lacking, the results of this study suggested that stand-alone surgical treatments for AF should be used as a 3rd-line approach, only after the failure of more conservative measures. It is important to note that patients with long-standing persistent AF may often suffer from a substantially increased burden of disease. There is a lack of data regarding the proper utilization of the hybrid Maze procedure in the treatment of this population and therefore further studies with a primary focus on these patients are needed.

The authors stated that this study had several drawbacks. Due to it being a retrospective, single-center analysis of electronic medical records, there was an inherent reliance on the accuracy of the records. As a result of the retrospective nature of the study, there was no way to accurately measure if the patients actually experienced any improvement of their AF symptoms following a procedure. Instead, the success of a procedure was based on the complete lack of recurrence of the arrhythmia. Also, because of the lack of randomization, there was no way to account for effects of other variables that were not measured at baseline. Lastly, like many other studies in this field, due to the limited utilization of surgical ablation procedures, there was a limited cohort size. Therefore, as discussed previously, the study was under-powered, and its inability to identify a difference in the efficacies of the Cox-Maze IV and the hybrid Maze did not imply their equality. Adequately powered studies in patients with symptomatic long-standing persistent AF are still needed to examine if the superior efficacy observed with surgical procedures might in fact out-weigh the risk of procedural complications and ultimately provide some benefit in mortality.
Vroomen and co-workers (2019) noted that success rates with conventional transvenous endocardial pulmonary vein isolation (PVI) in patients with persistent and long-standing persistent AF are variable due to advanced electrical and structural remodeling of the atria. As a consequence, more extensive endocardial lesions, minimally invasive thoracoscopic surgical techniques, and hybrid ablation (combining thoracoscopic epicardial surgical and endocardial catheter ablation) have been developed. The HARTCAP-AF trial hypothesizes that hybrid AF ablation is more effective than (repeated) transvenous endocardial catheter ablation in (long-standing) persistent AF, without increasing the number of associated major AEs. This randomized controlled trial (RCT) will include 40 patients with persistent or long-standing persistent AF who will be randomly assigned (1:1) to either hybrid ablation or (repeated) catheter ablation. The procedures and follow-up are conducted according to the guidelines. The primary effectiveness end-point is freedom from any supra-ventricular arrhythmia lasting longer than 5 mins without the use of Vaughan-Williams class I or III anti-arrhythmic drugs through 12 months of follow-up following the last procedure. In the catheter ablation arm, a 2nd procedure planned within 6 months after the index procedure is allowed for obtaining the primary end-point. Additionally, AEs, cost-effectiveness, and QOL data will be recorded. These researchers stated that catheter ablation and hybrid ablation have never been compared in a trial. This gap in the literature shows the need for this study to examine the safety and effectiveness of catheter and hybrid ablation in a randomized setting while also addressing associated cost-effectiveness to facilitate decision-making in the treatment of patients with non-paroxysmal AF.

Badhwar and associates (2018) reported the findings of 2 patients with long-standing AF refractory to medical management and with prior PVI, who underwent a new hybrid epicardial/endocardial subxyphoid approach for AF ablation and LAA ligation. Pulmonary vein and LA posterior wall isolation, as well as LAA exclusion were achieved in both patients. There were no procedural complications. Both patients remained in sinus rhythm; and were off anti-arrhythmic medications. The authors concluded that this report was the 1st demonstration of the feasibility of the subxyphoid pericardial access approach for epicardial ablation and LAA ligation and its use as a hybrid epicardial/endocardial approach for persistent and longstanding persistent AF refractory to medications and/or endocardial ablations. These researchers stated that as
technology advances, the possibility of a complete minimally invasive "Maze" procedure via the subxyphoid access approach or a completely percutaneous "Maze" procedure should be possible.

Sanchez and co-workers (2018) stated that AF is the most common cardiac arrhythmia. The incidence of AF increases with age and is associated with increased stroke, heart failure and mortality. Persistent and long-standing persistent AF is difficult to treat and often refractory to medical therapy and catheter ablation. These investigators reviewed the historical development of the surgical Cox-MAZE procedure and current hybrid and minimally invasive surgical approaches for the treatment of persistent and long-standing persistent AF; they also examined the role of concomitant PVI and LAA exclusion. An ablation pattern emulating the Cox-Maze surgical procedure is commonly needed to obtain maintenance of sinus rhythm in patients with persistent and long-standing persistent AF. Minimally invasive bilateral thorascopic surgical procedures can achieve a similar Cox-Maze lesion set; however, they are associated with increased AEs compared to catheter ablation. The authors stated that future prospective randomized studies are needed to confirm if the recently developed hybrid subxyphoid epicardial/endocardial procedure and percutaneous LAA ligation and catheter ablation are indeed as effective as surgical options with less AEs.

Ellis and colleagues (2020) noted that surgical hybrid ablation procedures have shown promise for maintaining sinus rhythm versus catheter ablation but are associated with increased peri-procedural AEs. These researchers examined the safety and efficacy of a new subxyphoid hybrid epicardial-endocardial AF ablation and LAA ligation approach for the treatment of persistent AF. Patients with symptomatic persistent AF (n = 33, mean age of 64 ± 9 years, 25 men) who had anti-arrhythmic drug therapy or prior catheter ablation was unsuccessful were referred for hybrid epicardial-endocardial AF ablation and LAA exclusion. LAA closure was confirmed by transesophageal echocardiographic (TEE) Doppler flow and/or computed tomographic angiography (CTA) 1 to 3 months post-ligation. The incidence of atrial tachycardia or AF recurrence, LAA closure, thromboembolic events, and post-operative complications were examined. All 33 patients underwent successful LAA ligation with epicardial ablation of the posterior left atrial wall, as well as endocardial pulmonary vein isolation and cavotricuspid isthmus ablation.
Freedom from atrial tachycardia or AF was 91% (20 of 22 patients) at 6 months, 90% (18 of 20 patients) at 12 months, 92% (11 of 12 patients) at 18 months, and 92% (11 of 12) at 24 months. There were no acute peri-procedural complications (less than 7 days); 30-day AEs included 2 patients with pericardial effusion requiring pericardiocentesis and 1 incisional hernia repair. There were no long-term complications, strokes, or deaths. LAA ligation was complete in 27 of 33 subjects (82%), with 6 subjects having leaks of less than 5 mm. The authors concluded that subxiphoid hybrid epicardial-endocardial ablation with LAA ligation was feasible, safe, and effective; future prospective, randomized studies are needed to validate these initial findings.

The authors stated that this study had several drawbacks. The study was a non-randomized, observational feasibility study with limitations inherent to all observational, non-randomized studies. There were variations within the procedural protocol, mainly concomitant versus staged endocardial ablation. However, the final ablation lesion set was similar, and there were no apparent differences in atrial arrhythmia recurrence outcomes. Furthermore, there was a mixed population of patients, because of selection of patients these investigators thought were reasonable candidates for this new procedure: those with symptomatic AF who had previous catheter ablation had been unsuccessful; and those with symptomatic AF who were being considered for LAA occlusion because of long-term intolerance to oral anti-coagulation (OAC) therapy and/or with LAAs deemed high risk (known history of LAA thrombus, sludge, or heavy spontaneous echocardiographic contrast despite OAC). Although the 2nd group of patients were de-novo and underwent more extensive procedures than just PVI, these researchers believed that epicardial exclusion of the LAA would prevent LAA thrombus formation as part of the lesion set, emulating the Cox-maze procedure. These patients were offered PVI and a Watchman device as an alternative option, as well as bilateral thoracoscopic epicardial ablation with an AtriClip (AtriCure). There were no differences in outcomes between the 2 groups of patients included in the study. In addition, only a few patients underwent endocardial mapping prior to LAA exclusion and epicardial ablation. There were no differences in outcomes between redo patients with isolated versus non-isolated pulmonary veins. However, with such small numbers, no conclusion can be made. The purpose of reporting the initial outcomes was to demonstrate the method of approximating a surgical
Cox-maze III procedure through a subxiphoid access and endocardial ablation approach and to support a potential rationale for future studies with a multi-center, randomized design using a uniform procedural protocol.

The Convergent Hybrid MAZE Procedure

Kress et al (2017) stated that variable outcomes exist following endocardial catheter ablation (CA) in medically refractory patients with persistent AF. A hybrid epicardial-endocardial approach has emerged as an alternative to endocardial ablation. These researchers compared the outcomes of hybrid ablation versus endocardial CA alone in patients with persistent and long-standing persistent AF. In 133 consecutive patients, 69 received endocardial ablation alone (PVI and RF CA [endo group]) and 64 received endocardial CA and epicardial ablation (hybrid group). Recurrence was defined as any arrhythmia following the 3-month blanking period. Patients were followed for a median of 16 months. The hybrid and endo groups were similar in age (61 ± 10 years versus 62 ± 8 years), body mass index (BMI; 35 ± 6 kg/m2 versus 35 ± 7 kg/m2), CHA2D2-VASc score (2 ± 1 versus 2 ± 1), and ejection fraction (EF; 54 ± 11 % versus 53 ± 8 %). The hybrid group had longer AF duration (median [inter-quartile range (IQR)] (12 months [IQR: 8 to 28 months] versus 7 months [IQR: 5 to 12 months]; p < 0.001) and more previous ablations (58 % versus 25 %; p < 0.001). Both groups had similar anti-arrhythmic drug use at follow-up (55 % versus 48 %). The hybrid group was less likely to have recurrence (37 % versus 58 %; p = 0.013) and repeat ablation (9 % versus 26 %; p = 0.012); and had an AF-free survival of 72 % versus 51 % (p = 0.01). The authors concluded that among patients with persistent AF, hybrid ablation was associated with less AF recurrence and fewer re-do ablations. Moreover, these researchers stated that prospective, large-scale, randomized trials are needed to validate these findings.

The authors stated that this study had several drawbacks. Data were collected retrospectively. Upon follow-up, patients had various methods of rhythm detection, and the higher incidence of ambulatory monitoring in the endocardial arm might have led to an increased detection of AF in this group. A prospective, randomized approach with consistent use of
Implantable arrhythmia monitoring is needed to conclude that the hybrid procedure has a significant impact on AF recurrence rates in patients with persistent and long-standing persistent AF.

DeLurgio et al (2020) noted that the limited effectiveness of endocardial CA for persistent and long-standing persistent AF treatment led to the development of a minimally invasive epicardial/endocardial ablation approach (Hybrid Convergent) to achieve a more comprehensive lesion set with durable transmural lesions. The multi-center randomized controlled CONVERGE trial (Convergence of Epicardial and Endocardial Ablation for the Treatment of Symptomatic Persistent AF) examined the safety of Hybrid Convergent and compared its effectiveness to CA for persistent and long-standing persistent AF treatment. A total of 153 patients were randomized 2:1 to Hybrid Convergent versus CA. Primary effectiveness was freedom from AF/atrial flutter/atrial tachycardia absent new/increased dosage of previously failed/intolerant class I/III anti-arrhythmic drugs through 12 months. Primary safety was major AEs through 30 days. CONVERGE allowed left atrium size of up to 6 cm and imposed no limits on AF duration, making it the only ablation trial to substantially include long-standing persistent-AF, that is, 42% patients with long-standing persistent AF. Of the 149 evaluable patients at 12 months, primary effectiveness was achieved in 67.7% (67/99) patients with Hybrid Convergent and 50.0% (25/50) with CA (p = 0.036) on/off previously failed anti-arrhythmic drugs and in 53.5% (53/99) versus 32.0% (16/50; p = 0.0128) respectively off anti-arrhythmic drugs. At 18 months using 7-day Holter, 74.0% (53/72) Hybrid Convergent and 55% (23/42) CA patients experienced greater than or equal to 90% AF burden reduction. A total of 2.9% (3/102) patients had primary safety events within 7 days, and 4.9% (5/102) between 8- and 30-day post-procedure. No deaths, cardiac perforations, or atrio-esophageal fistulas occurred. All but 1 primary safety event resolved. The authors concluded that the Hybrid Convergent procedure had superior effectiveness compared to the CA for the treatment of persistent and long-standing persistent AF.

The authors stated that the absence of empirical endocardial posterior wall ablation in the CA group was a limitation. Due to challenges with obtaining transmural posterior wall ablation while maintaining safety, it was difficult to state if the outcomes would have been better in the CA arm if posterior wall silencing was allowed. The study allowed only
irrigated RF catheters for endocardial ablation in both groups, primarily to maintain consistency. Cryoablation was not included. Furthermore, electrical isolation or exclusion of LAA was not performed. These researchers stated that future trials with endocardial cryoablation to assess incremental benefits of concomitant LAA exclusion and electrical isolation should be carried out.

Khan et al (2020) stated that the convergent procedure (CVP) is a hybrid ablation technique via a subxiphoid incision that has recently emerged as a therapeutic option for non-paroxysmal AF (npAF). By combining endocardial and epicardial ablation into a simultaneous or staged procedure, the pulmonary vein and posterior left atrium can be isolated with transmural lesion sets while minimizing the risk of pro-arrhythmic gaps that are a known limitation with endocardial linear lesion sets. These investigators reviewed the 12-month outcomes in patients who underwent CVP compared to those who underwent endocardial CA and surgical ablation (SA). They carried out a literature search using the PubMed database for publications related to CVP. Selected studies included detailed 12-month follow-up of patients, patient characteristics, peri-procedural complications, use of AADs, and monitoring method. A total of 5 studies with 340 patients who underwent CVP between January 2009 and March 2017 were selected for this review. A total of 8.5% of patients had paroxysmal AF (pAF), 42.2% had persistent AF (peAF), and 49.1% had long-standing persistent AF (lspAF). At 12 months, 81.9% of patients were in sinus rhythm, while 54.1% of patients were in sinus rhythm while not taking AADs. The overall complication rate was 10%. The authors concluded that CVP had better 1-year efficacy in eliminating AF when compared to CA; however, SA, specifically the Cox Maze IV, had lower rates of AF recurrence in the npAF patient population. These researchers noted that despite its promising 1-year efficacy rates, the peri-procedural complication rate for CVP was significantly higher than both CA and SA.

Furthermore, an UpToDate review on "Surgical ablation to prevent recurrent atrial fibrillation" (Lee, 2021) states that "Surgeons and cardiologists are now combining to perform some of the lesions surgically and some in the electrophysiology lab or operating room in a "hybrid" approach. There are three different types of approaches: right thoracotomy, subxiphoid, or bilateral thoracoscopic. The convergent
procedure is a subxyphoid approach that requires both surgery and catheter ablation in a single hospitalization to complete. Long-term follow-up is needed”.

**Concomitant Cox-Maze IV and Septal Myectomy for the Treatment of Hypertrophic Obstructive Cardiomyopathy**

Bakir et al (2022) noted that in patients with hypertrophic obstructive cardiomyopathy, AF is associated with heart failure and increased late mortality. However, the role of surgical ablation in these patients is not well-defined. These researchers examined the effectiveness of the concomitant Cox-Maze IV procedure in patients undergoing septal myectomy for hypertrophic obstructive cardiomyopathy. Between 2005 and 2019, a total of 347 patients who underwent septal myectomy at a single center were retrospectively reviewed. For patients with hypertrophic obstructive cardiomyopathy and AF who underwent a concomitant Cox-Maze IV procedure, freedom from atrial tachyarrhythmias (ATAs) on or off anti-arrhythmic drugs (AADs) was evaluated annually. Predictors of ATA recurrence were identified using Fine-Gray regression, with death as a competing risk. A total of 42 patients underwent concomitant septal myectomy and Cox-Maze IV procedures. The majority of patients, 69% (29 of 42), had paroxysmal AF with a 2.5-year median duration. Operative mortality was 7% (3 of 42). New York Heart Association (NYHA) functional class was reduced after surgery (p < 0.01). Rates of freedom from recurrent ATAs at 1- and 5-year intervals were 93% (27 of 29) and 100% (14 of 14), respectively. Rates of freedom from ATAs and AADs were 83% (24 of 29) and 100% (14 of 14) at the same time points, respectively. Increased left atrial diameter predicted 1st ATA recurrence (p < 0.01). Cerebrovascular accident risk was lower in patients with AF who underwent concomitant Cox-Maze IV and septal myectomy relative to myectomy only (p = 0.02). The authors concluded that late freedom from ATAs on or off AADs was excellent after Cox-Maze IV and septal myectomy. Although there was a higher-than-expected rate of peri-operative complications, the study results suggested that concomitant surgical ablation should be considered in selected patients with hypertrophic obstructive cardiomyopathy and AF.
Seco et al (2022) stated that AF is common in patients with hypertrophic cardiomyopathy, and significantly impacts mortality and morbidity. In patients with AF undergoing septal myectomy, concomitant surgery for AF may improve outcomes. In a systematic review performed according to PRISMA guidelines, these investigators examined the outcomes of combined septal myectomy and AF surgery. A total of 10 observational studies were identified, including 644 patients. Most patients had paroxysmal AF. The proportion with prior unsuccessful ablation ranged from 0 % to 19 %, and pre-operative left atrial diameter ranged from 44 ± 17 to 52 ± 8 mm. Cox-Maze IV (n = 311) was the most common technique used, followed by PVI (n = 222) and Cox-Maze III (n = 98). Patients with persistent or longstanding AF more frequently received Cox-Maze III/IV. Ranges of early post-operative outcomes included: mortality 0 % to 7 %, recurrence of atrial tachyarrhythmias 4.4 % to 48 %, cerebrovascular events 0 % to 1.5 %, and pace-maker insertion 3 % to 21%. Long-term data was limited. Freedom from atrial tachyarrhythmias at 1 year ranged from 74 % to 96 %, and at 5 years from 52 % to 100 %. Pre-operative predictors of late atrial tachyarrhythmia recurrence included left atrial diameter of greater than 45 mm, persistent or longstanding pre-operative AF and longer AF duration. The authors concluded that in patients with AF undergoing septal myectomy, the addition of ablation surgery added low overall risk to the procedure, and likely reduced the risk of recurrent AF in the long term. Moreover, these researchers stated that future randomized studies comparing septal myectomy with or without concomitant AF ablation are needed.

Guidelines from the American College of Cardiology and the American Heart Association on hypertrophic cardiomyopathy (2020) state: "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. Transaortic septal myectomy adds little to the risk of other cardiac procedures, and relief of LVOTO will minimize the risk of hemodynamic instability early postoperatively."
CPT Codes/ HCPCS Codes/ICD-10 Codes
Information in the [brackets] below has been added for clarification purposes. Codes requiring a 7th character are represented by “+”

<table>
<thead>
<tr>
<th>Code</th>
<th>Code Description</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td><strong>CPT codes covered if selection criteria are met:</strong></td>
</tr>
<tr>
<td>33254</td>
<td>Operative tissue ablation and reconstruction of atria, limited (e.g., modified maze procedure)</td>
</tr>
<tr>
<td>33256</td>
<td>Operative tissue ablation and reconstruction of atria, extensive (e.g., maze procedure); with cardiopulmonary bypass</td>
</tr>
<tr>
<td>+33257</td>
<td>Operative tissue ablation and reconstruction of atria, performed at the time of other cardiac procedure(s), limited (e.g., modified maze procedure) (List separately in addition to code for primary procedure)</td>
</tr>
<tr>
<td>+33259</td>
<td>Operative tissue ablation and reconstruction of atria, performed at the time of other cardiac procedure(s), extensive (e.g., maze procedure), with cardiopulmonary bypass (List separately in addition to code for primary procedure)</td>
</tr>
<tr>
<td></td>
<td><strong>CPT codes not covered for indications listed in the CPB:</strong></td>
</tr>
<tr>
<td>33255</td>
<td>Operative tissue ablation and reconstruction of atria, extensive (e.g., maze procedure); without cardiopulmonary bypass [hybrid Maze procedure]</td>
</tr>
<tr>
<td>+33258</td>
<td>Operative tissue ablation and reconstruction of atria, performed at the time of other cardiac procedure(s), extensive (e.g., maze procedure), without cardiopulmonary bypass (List separately in addition to code for primary procedure) [hybrid Maze procedure]</td>
</tr>
<tr>
<td>33265</td>
<td>Endoscopy, surgical; operative tissue ablation and reconstruction of atria, limited (e.g., modified maze procedure), without cardiopulmonary bypass</td>
</tr>
<tr>
<td>33266</td>
<td>operative tissue ablation and reconstruction of atria, extensive (e.g., maze procedure), without cardiopulmonary bypass</td>
</tr>
<tr>
<td></td>
<td><strong>Other CPT codes related to the CPB:</strong></td>
</tr>
<tr>
<td>62303 - 62305</td>
<td>Myelography via lumbar injection, including radiological supervision and interpretation</td>
</tr>
<tr>
<td>Code</td>
<td>Code Description</td>
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<td>----------------------------------------------------------------------------------</td>
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<tr>
<td>93015</td>
<td>Cardiovascular stress test using maximal or submaximal treadmill or bicycle exercise, continuous electrocardiographic monitoring, and/or pharmacological stress; with physician supervision, with interpretation and report</td>
</tr>
<tr>
<td>93224 - 93227</td>
<td>Electrocardiographic monitoring for 24 hours</td>
</tr>
<tr>
<td>93600 - 93660</td>
<td>Intracardiac electrophysiological procedures/studies</td>
</tr>
</tbody>
</table>

ICD-10 codes covered if selection criteria are met:

- I48.0 Atrial fibrillation [chronic]
- I48.1 Atrial flutter [chronic]

The above policy is based on the following references:


13. Cheng A. Surgical approaches to prevent recurrent atrial fibrillation. UpToDate [online serial]. Waltham, MA: UpToDate; reviewed December 2014.


65. Vroomen M, La Meir M, Maesen B, et al. Hybrid thoracoscopic surgical and transvenous catheter ablation versus transvenous catheter ablation in persistent and longstanding persistent atrial


Amendment to
Aetna Clinical Policy Bulletin Number: 0225 Maze Procedure

There are no amendments for Medicaid.

Revised 04/26/2022