**Clinical Policy Bulletin: Cardiac Catheter Ablation Procedures**

**Policy**

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

Aetna considers cardiac catheter ablation procedures medically necessary for any of the following arrhythmias:

I. **Atrial tachyarrhythmias** in members who meet any of the following:
   - Members resuscitated from sudden cardiac death due to atrial flutter or atrial fibrillation with a rapid ventricular response in the absence of an accessory pathway; or Members with a dual-chamber pacemaker and pacemaker-mediated tachycardia that cannot be treated effectively by drugs or by re-programming the pacemaker; or
   - Members with symptomatic atrial tachyarrhythmias such as those above but when drugs are not tolerated or the member does not wish to take them, even though the ventricular rate can be controlled; or
   - Members with symptomatic atrial tachyarrhythmias who have inadequately controlled ventricular rates; or
   - Members with symptomatic non-paroxysmal junctional tachycardia that is drug-resistant, drugs are not tolerated, or the member does not wish to take them.

II. **Atrioventricular nodal reentrant tachycardia (AVNRT)** in members who meet any of the following:
   - Members with sustained AVNRT identified during electrophysiological study or catheter ablation of another arrhythmia; or
   - Members with symptomatic sustained AVNRT that is drug-resistant or the member is drug-intolerant or does not desire long-term drug therapy; or
   - The finding of dual atrio-ventricular (AV) nodal pathway physiology and atrial echoes but without AVNRT during electrophysiological study in members suspected of having AVNRT clinically.

III. **Atrial tachycardia, flutter, and fibrillation** in members who meet any of the following:
   - Members with atrial fibrillation and evidence of a localized site(s) of origin when the tachycardia is drug-resistant or the member is drug-intolerant or does not desire long-term drug therapy (e.g., pulmonary vein isolation procedures); or
   - Members with atrial flutter that is drug-resistant or the member is drug-intolerant or does not desire long-term drug therapy; or
   - Members with atrial flutter/atrial tachycardia associated with paroxysmal atrial fibrillation when the tachycardia is drug-resistant or the member is drug-intolerant or does not
desire long-term drug therapy; or
- Members with atrial tachycardia that is drug-resistant or the member is drug-intolerant or does not desire long-term drug therapy.

IV. Accessory pathways (including Wolfe-Parkinson-White [WPW]) in members who meet any of the following:
- Asymptomatic members with ventricular pre-excitation whose livelihood or profession, important activities, insurability, or mental well-being or the public safety would be affected by spontaneous tachyarrhythmias or the presence of the electrocardiographic abnormality; or
- Members with a family history of sudden cardiac death; or
- Members with atrial fibrillation (or other atrial tachyarrhythmias) and a rapid ventricular response via the accessory pathway when the tachycardia is drug-resistant or the member is drug-intolerant or does not desire long-term drug therapy; or
- Members with atrial fibrillation and a controlled ventricular response via the accessory pathway; or
- Members with AV reentrant tachycardia or atrial fibrillation with rapid ventricular rates identified during electrophysiological study of another arrhythmia; or
- Members with symptomatic AV reentrant tachycardia that is drug-resistant or the member is drug-intolerant or does not desire long-term drug therapy.

V. Ventricular tachycardia (VT) in members who meet any of the following:
- Members with bundle branch reentrant ventricular tachycardia; or
- Members with sustained monomorphic VT and an implantable cardioverter-defibrillator (ICD) who are receiving multiple shocks not manageable by re-programming or concomitant drug therapy; or
- Members with symptomatic sustained monomorphic VT when the tachycardia is drug-resistant or the member is drug-intolerant or does not desire long-term drug therapy; or
- Non-sustained VT that is symptomatic when the tachycardia is drug-resistant or the member is drug-intolerant or does not desire long-term drug therapy.

VI. Operative Ablation

Aetna considers operative ablation medically necessary. This procedure may be used to eliminate AV condition defects. The procedure is performed through an incision to ablate (destroy) the arrhythmic area of the heart.

Aetna considers cardiac catheter ablation procedures experimental and investigational for all other indications, including any of the following arrhythmias, as there is insufficient evidence in the peer-reviewed medical literature of the effectiveness of cardiac catheter ablation for these indications:
- Benign non-sustained VT that does not cause symptoms; or
- Hypertrophic cardiomyopathy; or
- Multifocal atrial tachycardia (MAT); or
- Other uses of radiofrequency catheter ablation not indicated above (e.g., AV junction ablation in combination with pacemaker implantation for symptomatic drug-refractory atrial fibrillation); or
- Unstable, rapid, multiple or polymorphic VT that cannot be adequately localized by mapping techniques.

Aetna considers intra-myocardial infusion-needle catheter ablation for ventricular tachycardia experimental and investigational because its effectiveness has not been established.

Notes: For members who undergo an electrophysiology study on the same day as an ablation, an electrophysiologic study is considered medically necessary if no prior electrophysiology study has been performed within the previous 3 months. Two electrophysiologists are required to perform the ablation.
-- 1 to manipulate the catheters, and the other to guide the precise location for the ablation utilizing electrogram analysis and pacing. The procedure includes temporary pacemaker placement if indicated. When ablation of the His-bundle is indicated, a permanent pacemaker will always be placed because the ablation has caused a complete heart block.

Notes: The use of the CARTO system (an intra-cardiac electrophysiological 3-D mapping system) is considered medically necessary for guiding radiofrequency ablation in the treatment of arrhythmias.

See also CPB 0225 - Maze Procedure.

Background

Catheter ablation is a therapeutic technique using a tripolar electrode catheter to eliminate conduction defects, which cause tachycardia. This technique involves a high level of current, which is channeled through a catheter to destroy the arrhythmic area of the heart. It treats supraventricular tachycardia by ablating or modulating the atrio-ventricular (AV) node or ablating accessory conduction pathways; it treats ventricular tachycardia by ablating the arrhythmogenic focus (as an alternative to open heart surgical techniques). Catheter ablation is an acceptable alternative to long-term drug therapy. The role of catheter ablation as primary therapy for several arrhythmias has been described in position papers or technology assessments by the American Medical Association, the American College of Cardiology, and the North American Society of Pacing and Electrophysiology.

Bradley and Shen (2007) stated that non-randomized studies suggested that AV junction ablation and pacemaker implantation may improve quality of life, ejection fraction, and exercise tolerance in patients with symptomatic drug-refractory atrial fibrillation. These researchers examined if recent randomized trials support the use of AV junction ablation in combination with conventional right ventricular pacemaker therapy or cardiac resynchronization therapy (CRT) in atrial fibrillation. They performed a meta-analysis of randomized trials comparing AV junction ablation versus drugs or CRT versus right ventricular pacing for atrial fibrillation. Six randomized trials with 323 patients compared AV junction ablation versus pharmacotherapy were included. The majority of these trials did not individually report a statistically significant improvement in survival, stroke, hospitalization, functional class, atrial fibrillation-associated symptoms, left ventricular ejection fraction, exercise capacity, healthcare costs, or quality of life. Overall, all-cause mortality was 3.5 % for AV junction ablation patients and 3.3 % for controls (relative risk 1.18, 99 % confidence interval [CI]: 0.26 to 5.22). Three randomized trials with 347 patients compared CRT versus right ventricular pacing in atrial fibrillation. These trials did not individually report a statistically significant improvement in survival, stroke, hospitalization, exercise capacity, or healthcare costs. Cardiac resynchronization therapy was associated with a statistically significant improvement in ejection fraction in 2 of the 3 trials. Overall, CRT was associated with a trend toward reduced all-cause mortality relative to controls (relative risk 0.51, 99 % CI: 0.22 to 1.16). All-cause mortality was 7.1 % for CRT patients and 14 % for controls. The authors concluded that limited randomized trial data have been published regarding AV junction ablation in combination with conventional pacemaker therapy or CRT for atrial fibrillation. They stated that large-scale randomized trials are needed to assess the effectiveness of these therapies.

Khan and associates (2008) stated that pulmonary-vein (PV) isolation (ablation) is increasingly being used to treat atrial fibrillation in patients with heart failure. In this prospective, multi-center clinical trial, these investigators randomly assigned patients with symptomatic, drug-resistant atrial fibrillation, an ejection fraction of 40 % or less, and New York Heart Association (NYHA) class II or III heart failure to undergo either PV isolation or AV-node ablation with biventricular pacing. All patients completed the Minnesota Living with Heart Failure questionnaire (scores range of 0 to 105, with a higher score indicating a worse quality of life) and underwent echocardiography and a 6-min walk test (the composite primary end point). Over a 6-month period, patients were monitored for both symptomatic and asymptomatic episodes of atrial fibrillation. A total of 41 patients underwent PV isolation, and 40
underwent AV-node ablation with bi-ventricular pacing; none was lost to follow-up at 6 months. The composite primary end point favored the group that underwent PV isolation, with an improved questionnaire score at 6 months (60 versus 82 in the group that underwent AV-node ablation with bi-ventricular pacing; p < 0.001), a longer 6-min walk test (340 m vs 297 m, p < 0.001), and a higher ejection fraction (35 % versus 28 %, p < 0.001). In the group that underwent PV isolation, 88 % of patients receiving anti-arrhythmic drugs (AADs) and 71 % of those not receiving such drugs were free of atrial fibrillation at 6 months. In the group that underwent PV isolation, PV stenosis developed in 2 patients, peri-cardial effusion in 1, and pulmonary edema in another; in the group that underwent AV-node ablation with biventricular pacing, lead dislodgment was found in 1 patient and pneumothorax in another. The authors concluded that PV isolation was superior to AV-node ablation with bi-ventricular pacing in patients with heart failure who had drug-refractory atrial fibrillation.

Rottlaender et al (2009) stated that cryothermal ablation is a new method in cardiac electrophysiology for the percutaneous catheter ablation of cardiac arrhythmias. Cryothermal mapping allows functional evaluation of a particular site prior to ablation. Thus, the targeted tissue may be confirmed as safe for ablation. This approach is useful in high-risk ablations (e.g., next to the AV node). In cryothermal ablation, pressurized liquid nitrogen is delivered to the tip of the ablation catheter; cooling of the tip is temperature-controlled. Cryothermal balloons are also available, in addition to standard cryothermal catheters, for the isolation of pulmonary veins. The tissue freezing provides high catheter stability. Cryothermal lesions have a similar depth to radiofrequency energy, but area and volume of the lesions are reduced. Furthermore, they are well demarked and the incidence of thrombus-formation is reduced. Cryothermal ablation has been evaluated for the treatment of AVNRT, accessory pathways, atrial flutter, atrial fibrillation and ventricular tachycardia (VT) originating in the right ventricular outflow tract. Current experience indicates that the method safe and painless. However, its use seems to be limited by a longer ablation time and lower efficacy. The authors stated that further studies evaluating long-term success of cryothermal ablation are needed. For high-risk ablations, cryothermal energy is helpful and should be used for para-Hisian accessory pathways and difficult cases of AVNRT. It has a widely demonstrated safety profile. The clinical efficacy will have to be evaluated in further studies.

Furthermore, in a review on new technologies in atrial fibrillation ablation, Burkhardt and Natale (2009) stated that cryoablation therapy may not be as durable as radiofrequency, as observed in some studies of supraventricular tachycardia ablation. At this point, balloon-based ablation systems (cryoablation, laser, and high-frequency ultrasound) have not been proven to be as effective as current techniques and do not appear to save procedure time.

Computer-based electro-anatomical mapping systems are able to reconstruct cardiac anatomy and provide a straight-forward representation of chamber activation. These systems capture and display details of intra-cardiac physiology and mark the site of interventions. Currently, several mapping technologies are available in the electro-physiological laboratories (e.g., the CARTO system, and the EnSite 3000). Electro-anatomic mapping systems combine 3 important functionalities: (i) non-fluoroscopic localization of electro-physiological catheters in three-dimensional (3-D) space; (ii) analysis and 3-D display of activation sequences computed from local or calculated electrograms, and 3-D display of electrogram voltage ("scar tissue"); and (iii) integration of this "electro-anatomic" information with non-invasive images of the heart (mainly computed tomography or magnetic resonance images). Although better understanding and ablation of complex arrhythmias mostly relies on the 3-D integration of catheter localization and electrogram-based information to illustrate re-entrant circuits or areas of focal initiation of arrhythmias, the use of electro-anatomic mapping systems in atrial fibrillation is currently based on integration of anatomic images of the left atrium and non-fluoroscopic visualization of the ablation catheter. Their use in the treatment of atrial fibrillation is mainly driven by safety considerations such as shorter fluoroscopy and procedure times, or visualization of cardiac (pulmonary veins) and extra-cardiac (esophagus) structures that need to be protected during the procedure (Knackstedt et al, 2008).

Liu and colleagues (2005) evaluated the characteristics of the CARTO system and the Ensite/NavX
system and compared them on the aspects of procedural parameters and clinical effectiveness. A total of 75 cases with paroxysmal or chronic symptomatic atrial fibrillation were randomly assigned to circumferential pulmonary vein ablation (CPVA) procedure guided by the Ensite/NavX system (group I, n = 40) and by the CARTO system (group II, n = 35). After successful trans-septal procedure, the geometry of left atrium was created under the guidance of the 2 systems. Radiofrequency energy was applied to circumferentially ablate tissues out of pulmonary veins' (PVs') ostia. In cases with chronic atrial fibrillation, linear ablation was applied to modify the substrate of left atrium (LA). The endpoint of the procedure was complete PVs isolation. Seventy-five cases underwent the procedure successfully. The total procedure and fluoroscopic durations in group II were significantly shorter than in group I [(150 +/- 23) mins and (18 +/- 17) mins versus (170 +/- 34) mins and (25 +/- 16) mins, p = 0.03 and 0.04, respectively]. There was no significant difference in the fluoroscopic and procedure durations for geometry creation between group I and group II [(8 +/- 4) mins and (16 +/- 11) mins versus (5 +/- 4) mins and (14 +/- 8) mins, respectively]. The fluoroscopic durations for CPVA were (15 +/- 5) mins in group I versus (10 +/- 6) mins in group II (p = 0.05), and the CPVA procedural durations were significantly shorter in group II than in group I [(18 +/- 11) mins versus (25 +/- 10) mins, p = 0.04]. Atrial fibrillation was terminated by radiofrequency delivery in 14 cases (35 %) in group I versus 5 cases (14 %) in group II (p = 0.035). After CPVA, complete PV isolation was attained in 26 cases (65 %) in group I versus 11 cases (31 %) in group II (p = 0.004). During a mean follow-up of 7 months, 32 (80 %) cases in group I and 24 (69 %) cases in group II were arrhythmia-free (p = 0.06). One case developed peri-cardium effusion and another case was found to have intestinal artery thrombosis in group II. One case had moderate hemothorax in group I. All the complications were cured by proper treatment. No PV stenosis was observed. The authors concluded that the CPVA procedure for atrial fibrillation is safe and effective. Although there is difference between the CARTO system and the Ensite/NavX system, the CPVA procedure guided by either of them yields similar clinical results.

Suleiman et al (2007) reported the early and late outcome in patients with different arrhythmias treated with radiofrequency ablation combined with the CARTO mapping and navigation system. The study cohort comprised 125 consecutive patients with different cardiac arrhythmias referred for mapping and/or ablation procedures using the CARTO system. Forty patients (32 %) had previous failed conventional ablation or mapping procedures and were referred by other centers. The arrhythmia included atrial fibrillation (n = 13), atrial flutter (n = 38), atrial tachycardia (n = 25), ventricular tachycardia (n = 24), arrhythmogenic right ventricular dysplasia (n = 9), and supra-ventricular tachycardia (n = 16). During the study period, a total of 125 patients (mean age of 49 +/- 19 years, 59 % males) underwent electro-physiological study and electro-anatomic mapping of the heart chambers. Supra-ventricular arrhythmias were identified in 92 patients (73 %) and ventricular arrhythmias in 33 (27 %). Acute and late success rates, defined as termination of the arrhythmia without anti-arrhythmic drugs, were 87 % and 76 % respectively. One patient (0.8 %) developed a clinically significant complication. The authors concluded that the CARTO system increased the safety, efficacy and efficiency of radiofrequency ablation.

Hindricks et al (2009) stated that radiofrequency catheter ablation of typical atrial flutter is one of the most frequent indications for catheter ablation in electrophysiology laboratories today. Clinical utility of electro-anatomic mapping systems on treatment results and resource utilization compared with conventional ablation has not been systematically investigated in a prospective multi-center study. In this prospective, randomized multi-center study, the findings of catheter ablation to cure typical atrial flutter using conventional ablation strategy were compared with electro-anatomically guided mapping and ablation (using the CARTO system). Primary endpoints of the study were procedure duration and fluoroscopy exposure time, secondary endpoints were acute success rate, recurrence rate, and resource utilization. A total of 210 patients (169 men, 41 women, mean age of 63 +/- 10 years) with documented typical atrial flutter were included in the study. Acute ablation success, that is, demonstration of bi-directional isthmus block, was achieved in 99 of 105 patients (94 %) in the electro-anatomically guided ablation group and in 102 of 105 patients (97 %) in the conventional ablation group (p > 0.05). Total procedure duration was comparable between both study groups (99 +/- 57 mins versus 88 +/- 54 mins, p > 0.05). Fluoroscopy exposure time was significantly shorter in the
electro-anatomically guided ablation group (7.7 +/- 7.3 mins versus 14.8 +/- 11.9 mins; p < 0.05). Total recurrence rate of typical atrial flutter at 6 months of follow-up was comparable between the 2 groups (respectively for the CARTO and conventional group 6.6 % versus 5.7 %, p > 0.05). The material costs per procedure in the electro-anatomically guided and conventional groups (NaviStar DS versus Celsius DS) was 3035 Euro (USD 3,870) and 2133 Euro (USD 2,720), respectively. The authors concluded that this multi-center study documented that cavo-tricuspid isthmus ablation to cure typical atrial flutter was highly effective and safe, both in the conventional and the electro-anatomically guided ablation group. The use of electro-anatomical-mapping system significantly reduced the fluoroscopy exposure time by almost 50 %, however, at the expense of increased cost of the procedure.

Suleiman et al (2007) noted that catheter ablation is assuming a larger role in the management of patients with cardiac arrhythmias. Conventional fluoroscopic catheter mapping has limited spatial resolution and involves prolonged fluoroscopy. The non-fluoroscopic electro-anatomic mapping technique (CARTO) has been developed to overcome these drawbacks. These researchers reported the early and late outcome in patients with different arrhythmias treated with radiofrequency ablation combined with the CARTO mapping and navigation system. The study cohort comprised 125 consecutive patients with different cardiac arrhythmias referred to our center from January 1999 to July 2005 for mapping and/or ablation procedures using the CARTO system. Forty patients (32 %) had previous failed conventional ablation or mapping procedures and were referred by other centers. The arrhythmia included atrial fibrillation (n = 13), atrial flutter (n = 38), atrial tachycardia (n = 25), ventricular tachycardia (n = 24), arrhythmogenic right ventricular dysplasia (n = 9), and supraventricular tachycardia (n = 16). During the study period, a total of 125 patients (mean age of 49 +/- 19 years, 59 % males) underwent electrophysiological study and electro-anatomic mapping of the heart chambers. Supraventricular arrhythmias were identified in 92 patients (73 %) and ventricular arrhythmias in 33 (27%). Acute and late success rates, defined as termination of the arrhythmia without anti-arrhythmic drugs, were 87 % and 76 % respectively. One patient (0.8 %) developed a clinically significant complication. The authors concluded that the CARTO system advances the understanding of arrhythmias, and increases the safety, efficacy and efficiency of radiofrequency ablation.

Colín Lizalde Lde (2007) stated that in 1992 the radiofrequency ablation program was started, with very good results in patients with supraventricular tachycardias and normal hearts or minimal structural defects. Nevertheless, the results are not as good for the patients with structural defects, which are actually seen more frequently, those are cases with more complex arrhythmias, are patients with cardiac surgery that show a complex arrhythmogenic substrate or patients previously treated with conventional ablation which tachycardia recurs. In these cases, the electro-anatomic CARTO system has been very useful. In the last 2 years, 74 procedures with the CARTO system were performed, of which 56 have been supraventricular arrhythmias, improving substantially the success rates. The authors concluded that the electro-anatomical mapping allowed the more accurate identification of the arrhythmogenic substrate, achieving better success rates in recurrent tachycardia after conventional ablation, or in cases with more complex arrhythmogenic substrates.

Wu et al (2013) examined acute and long-term outcome after catheter ablation of supraventricular tachycardia in patients after the Mustard or Senning operation for D-transposition of the great arteries. This single-center retrospective analysis included 26 patients (mean age of 28.7 ± 6.7 years, 8 females) after Mustard (n = 15) or Senning (n = 11) operation who underwent catheter ablation for intra-atrial re-entrant tachycardia (IART) or AV nodal re-entrant tachycardia (AVNRT) from January 2004 to May 2011. The electrophysiological studies were performed using a 3-D mapping system (CARTO). Remote magnetic navigation (RMN) was available since 2008. Follow-up on an out-patient basis was conducted 3, 6, and 12 months after ablation and yearly thereafter. In the 26 patients, 34 procedures were performed (1 procedure n = 19; 2 procedures, n = 6; and 3 procedures, n = 1). Overall, 34 tachycardia forms (IART n = 30; AVNRT n = 4) were ablated manually (n = 25) or by RMN (n = 9). Acute success reached in 29/34 forms (85.3 %). Mean fluoroscopy time (FT) was 28.2 ± 20.7 mins and mean procedure duration (PD) was 290.9 ± 107.6 mins. After a mean follow-up of 34.1 ± 24.5 months, 25/26 (96.2 %) patients were free from IART or AVNRT. In the 9 RMN ablations (mean follow-up of 14.2 ± 5.8 months) acute and long-term success was 100 %. Fluoroscopy time and PD
were significantly reduced using RMN compared with manual ablation (11.9 ± 6.2 versus 34.6 ± 20.6 mins, 225.7 ± 24.1 versus 312 ± 118.2 mins, p = 0.02). The authors concluded that catheter ablation of IART or AVNRT in patients post-Mustard/Senning operation for D-transposition of the great arteries (d-TGA) has a high acute success rate. The recurrence rate for IART is about 30%; however, after a second ablation, long-term results are excellent. They stated that remote magnetic navigation seems to improve single-procedure acute and long-term success and significantly reduces FT and PD.

Svintsova et al (2013) stated that the use of radiofrequency ablation (RFA) for the management of supraventricular tachycardia (SVT) in infants and small children remains controversial. The aim of this study was to evaluate the safety and efficacy of RFA in critically ill small children (less than 1 year of age) with drug-resistant tachycardia accompanied by arrhythmogenic cardiomyopathy and heart failure. The study included 15 patients age 5.3 ± 3.7 months. Wolff-Parkinson-White syndrome and atrial tachycardia were detected in 8 (53.3%) and 7 (46.7%) of patients, respectively. Patients with structural heart pathology, including congenital heart diseases and laboratory-confirmed myocarditis, were excluded from the study. Indications for RFA included drug-refractory SVT accompanied by arrhythmogenic cardiomyopathy and heart failure. Unsuccessful ablation was observed in 2 1-month-old patients who underwent successful ablation 3 months later. The follow-up period ranged from 0.5 to 8 years (average of 3.9 years). Only 1 patient (6.7%) had tachycardia recurrence 1 month after RFA. The short- and long-term RFA success rates were 86.7 and 93.3%, respectively. The study did not show any procedure-related complications. Heart failure disappeared within 5 to 7 days. Complete normalization of heart chamber sizes was documented within 1 month after effective RFA. A 3-D CARTO system (Biosense Webster, Inc.) was used in 3 patients with body weight greater than 7 kg. The use of the CARTO system resulted in a remarkable decrease of the fluoroscopy time without vascular injury or other procedure-related complications in all cases. The authors concluded these findings suggested that RFA may be considered the method of choice for SVT treatment in small children when drug therapy is ineffective and arrhythmogenic cardiomyopathy progresses.

Spar et al (2013) noted that traditional imaging for ablation of supraventricular tachycardia has been fluoroscopy, although 3-D electro-anatomic mapping (3D) has been demonstrated to reduce radiation exposure. This study compared a technique for the reduction of radiation, low-dose fluoroscopy (LD), with standard-dose fluoroscopy (SD) and 3D with SD (3D-SD). This was a single institutional retrospective cohort study. All patients undergoing initial ablation for AV reentrant tachycardia (AVRT) or AV nodal reentrant tachycardia (AVNRT) from 2009 to 2012 were reviewed and divided into 3 groups: (i) SD, (ii) 3D (CARTO or NavX) with SD, or (iii) LD. LD uses the same equipment as SD but included customized changes to the manufacturer's lowest settings by decreasing the requested dose to the detector. Primary outcomes were fluoroscopy time and dose area product exposure. A total of 181 patients were included. The median age was 15.0 years (3.3 to 20.8); 59% had AVRT, 35% had AVNRT, and 6% had both AVRT and AVNRT. LD decreased the dose area product (DAP) compared with SD (637.0 versus 960.1 cGy*cm², p = 0.01) with no difference in fluoroscopy time. 3D-SD decreased fluoroscopy time compared with SD (9.9 versus 18.3 minutes, p < 0.001) with DAP of 570.1.0 versus 960.1 cGy*cm² (p = 0.16). LD and 3D-SD had comparable DAP (637.0 versus 570.1 cGy*cm², p = 0.67), even though LD had significantly longer fluoroscopy time (19.9 versus 9.9 minutes, p < 0.001). The authors concluded that LD during catheter ablation of AVRT and AVNRT significantly reduced the DAP compared with SD and had similar radiation exposure compared with 3D with SD.

Pass et al (2015) noted that “ALARA - As Low As Reasonably Achievable” protocols reduce patient radiation dose. Addition of electro-anatomical mapping may further reduce dose. From 6/11 to 4/12, a novel ALARA protocol was utilized for all patients undergoing supraventricular tachycardia ablation, including low frame rates (2 to 3 frames/second), low fluoro dose/frame (6 to 18 nGy/frame), and other techniques to reduce fluoroscopy (ALARA). From 6/12 to 3/13, use of CARTO® 3 (C3) with “fast anatomical mapping” (ALARA+C3) was added to the ALARA protocol. Intra-vascular echo was not utilized. Demographics, procedural, and radiation data were analyzed and compared between the 2 protocols. A total of 75 patients were included: 42 ALARA patients, and 33 ALARA+C3 patients. Patient demographics were similar between the 2 groups. The acute success rate in ALARA was 95
and 100% in ALARA + C3; no catheterization-related complications were observed. Procedural time was 125.7 minutes in the ALARA group versus 131.4 in ALARA+C3 (p = 0.36). Radiation doses were significantly lower in the ALARA + C3 group with a mean air Kerma in ALARA + C3 of 13.1 ± 28.3 mGy (SD) compared with 93.8 ± 112 mGy in ALARA (p < 0.001). Mean dose area product was 92.2 ± 179 uGym2 in ALARA + C3 compared with 584 ± 687 uGym2 in ALARA (p < 0.001). Of the 33 subjects (42%) in the ALARA + C3 group, 14 received less than or equal to 1 mGy exposure. The ALARA + C3 dosages are the lowest reported for a combined electroanatomical-fluoroscopy technique. The authors concluded that addition of CARTO® 3 to ALARA protocols markedly reduced radiation exposure to young people undergoing supraventricular tachycardia ablation while allowing for equivalent procedural efficacy and safety.

American College of Cardiology guidelines on ventricular arrhythmias and sudden cardiac death (Zipes, et al., 2006) state that 3-dimensional mapping systems permit anatomical reconstructions and correlation of EP characteristics with anatomy. These systems have led to an approach whereby circuits can be mapped during sinus rhythm and can facilitate ablation in the ischemic patient who often does not tolerate VT well. Use of these techniques may result in better long-term success rates. American College of Cardiology guidelines on supraventricular arrhythmias (Blomström-Lundqvist, et al., 2003) state that, in patients with prior surgical repair, both CTI-dependent and non–CTI-dependent (so-called “incisional” or scar) atrial flutter occur and can coexist in a single patient. If catheter ablation is warranted… ablation may be best performed in an experienced center with advanced, three-dimensional mapping equipment for defining non-CTI-dependent arrhythmias. Heart Rhythm Society guidelines on atrial fibrillation (Calkins, et al., 2012) state that it is well known that mapping and ablation of atrial fibrillation (AF) require accurate navigation in the LA. This can be obtained using standard fluoroscopy or more commonly with electroanatomic mapping systems that combine anatomic and electrical information by a catheter point-by-point mapping, allowing an accurate anatomic reconstruction of a 3D shell of the targeted cardiac chamber. The use of these 3D mapping systems has been demonstrated to reduce fluoroscopy duration.

Lawrenz and colleagues (2011) examined the safety and effectiveness of endocardial radiofrequency ablation of septal hypertrophy (ERASH) for left ventricular outflow tract (LVOT) gradient reduction in hypertrophic obstructive cardiomyopathy (HOCM). A total of 19 patients with HOCM were enrolled; in 9 patients, the left ventricular septum was ablated, and in 10 patients, the right ventricular septum was ablated. Follow-up examinations (echocardiography, 6-min walk test, bicycle ergometry) were performed 3 days and 6 months after ERASH. After 31.2 +/- 10 radiofrequency pulses, a significant and sustained LVOT gradient reduction could be achieved (62% reduction of resting gradients and 60% reduction of provoked gradients, p = 0.0001). The 6-min walking distance increased significantly from 412.9 +/- 129 m to 471.2 +/- 139 m after 6 months, p = 0.019); and New York Heart Association functional class was improved from 3.0 +/- 0.7 to 1.6 +/- 0.7 (p = 0.0001). Complete AV block requiring permanent pacemaker implantation occurred in 4 patients (21%); 1 patient had cardiac tamponade. The authors concluded that ERASH is a new therapeutic option in the treatment of HOCM, allowing significant and sustained reduction of the LVOT gradient as well as symptomatic improvement with acceptable safety by inducing a discrete septal contraction disorder. They stated that ERASH may be suitable for patients not amenable to transcoronary ablation of septal hypertrophy or myectomy. The drawbacks of this study included the lack of a control group, small sample size and short-term follow-up. These findings need to be validated by more research.

Sreeram et al (2011) evaluated the effectiveness of radiofrequency catheter ablation (RFCA) in the treatment of HOCM in children. In 32 children, at a median age of 11.1 (range of 2.9 to 17.5) years and weight of 31 (15 to 68) kg, ablation of the hypertrophied septum was performed using a cool-tip ablation catheter via a femoral arterial approach. The median number of lesions was 27 (10 to 63) and fluoroscopic time was 24 (12 to 60) mins. The majority of patients showed an immediate decrease in the catheter pullback gradient (mean 78.5 +/- 26.2 mm Hg pre-RFCA versus mean 36.1 +/- 16.5 mm Hg post-RFCA, p < 0.01) and a further reduction in the Doppler echocardiographic gradient (mean 96.9 +/- 27.0 mm Hg pre-RFCA versus 32.7 +/- 27.1 mm Hg post-RFCA, p < 0.01) at follow-up. One patient died due to a paradoxical increase in left ventricular outflow tract obstruction, and another had
McLellan et al (2013) noted that pulmonary vein reconnection is a major limitation of pulmonary vein isolation (PVI) for symptomatic AF. Adenosine (ADO) may unmask dormant PV conduction and facilitate consolidation of PV isolation. These investigators performed a systematic review of the literature to determine the impact of routine ADO administration on clinical outcomes in patients undergoing PVI. References and electronic databases reporting AF ablation and ADO following PVI were searched through to July 31, 2012. A total of 6 studies included 544 patients to assess the impact of catheter ablation to target ADO-induced PV reconnection on AF ablation outcome and 3 studies included 612 patients to assess the impact of ADO testing on AF ablation outcome. Relative risks were calculated and combined in a meta-analysis using random effects modeling. Routine ADO testing for PV reconnection with additional targeted ablation resulted in a significant increase in freedom from AF post-PVI (risk ratio [RR] 1.25; 95 % CI: 1.12 to 1.40; p < 0.001). However, within the group of patients undergoing ADO testing, those with reconnection identified a population with a trend to reduction in freedom from AF despite the use of further targeted ablation in the reconnection group (RR 0.91 with 95 % CI: 0.81 to 1.03; p = 0.15). The authors concluded that routine ADO testing is associated with an improvement in freedom from AF post-PVI. Paradoxically acute ADO-induced PV reconnection may portend a greater likelihood of AF recurrence despite additional ablation. The authors stated that randomized controlled trials (RCTs) are needed to determine the role of ADO testing post-PVI.

Macle et al (2012) stated that PVI has emerged as an effective therapy for paroxysmal AF. However, AF recurs in up to 50 % of patients, generally because of recovery of PV conduction. Adenosine given during the initial procedure may reveal dormant PV conduction, thereby identifying the need for additional ablation, leading to improved outcomes. The Adenosine Following Pulmonary Vein Isolation to Target Dormant Conduction Elimination (ADVICE) study is a prospective multi-center RCT assessing the impact of ADO-guided PVI in preventing AF recurrences. Patients undergoing a first PVI procedure for paroxysmal AF will be recruited. After standard PVI is completed, all patients will receive intravenous ADO in an attempt to unmask dormant conduction. If dormant conduction is elicited, patients will be randomized to no further ablation (control group) or additional ADO-guided ablation until dormant conduction is abolished. If no dormant conduction is revealed, randomly selected patients will be followed in a registry. The primary outcome is time to first documented symptomatic AF recurrence. Assuming that dormant conduction is present in 50 % of patients post-PVI and symptomatic AF recurs in 45 % of controls, 244 patients with dormant conduction will be needed to obtain greater than 90 % power to detect a difference of 20 %. Thus, a total of 488 patients will be enrolled and followed for 12 months. The authors concluded that the ADVICE trial will examine if a PVI strategy incorporating elimination of dormant conduction unmasked by intravenous ADO will decrease the rate of recurrent symptomatic AF compared with standard PVI.

Cheung et al (2013) noted that ADO can unmask dormant pulmonary vein conduction following PVI. Adenosine can also induce ectopy in electrically silent PVs following isolation, possibly via activation of autonomic triggers. These researchers sought to identify the implications of ADO-induced PV ectopy for AF recurrence following PVI. A total of 152 patients (age of 60 ± 11 years; 63 % paroxysmal AF) undergoing PVI for AF were studied. After each PV was isolated, ADO was administered and the presence of ADO-induced PV reconnection and PV ectopy were recorded. Dormant conduction was targeted with additional ablation. Adenosine-induced PV ectopy was seen in 45 (30 %) patients and dormant conduction was seen in 44 (29 %) patients. After a median follow-up of 374 days, 48 (32 %) patients had recurrent AF after a single ablation procedure. Rates of freedom from AF among patients with ADO-induced PV ectopy were significantly lower than patients without ADO-induced PV ectopy (63 % versus 76 % at 1 year; log rank = 0.014). Rates of freedom from AF among patients with dormant conduction were also lower than patients without dormant conduction (64 % versus 76 % at 1 year; log rank = 0.014).

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year; log rank = 0.062). With multi-variate analysis, ADO-induced PV ectopy was found to be the only independent predictor of AF after PVI (HR 1.90; 95 % CI: 1.06 to 3.40; p = 0.032). The authors concluded that ADO-induced PV ectopy is a predictor of recurrent AF following PVI and may be a marker of increased susceptibility to autonomic triggers of AF.

Morales et al (2013) examined if dormant conduction across the cavo-tricuspid isthmus (CTI) may be revealed by ADO after ablation-induced bi-directional block, and its association with recurrent flutter. Patients undergoing catheter ablation for CTI-dependent flutter were prospectively studied. After confirming bi-directional block across the CTI by standard pacing maneuvers, ADO (greater than or equal to 12 mg IV) was administered to assess resumption of conduction, followed by isoproterenol (ISP) bolus. Further CTI ablation was performed for persistent (but not transient) resumption of conduction. Bi-directional block across the CTI was achieved in all 81 patients (63 males), age of 61.2 ± 11.0 years. The trans-CTI time increased from 71.9 ± 18.1 milliseconds pre-ablation to 166.2 ± 26.4 milliseconds post-ablation. Adenosine elicited resumption of conduction across the CTI in 7 patients (8.6 %), 2 of whom had transient recovery. No additional patient with dormant conduction was identified by ISP. Over a follow-up of 11.8 ± 8.0 months, atrial flutter recurred in 4 (4.9 %) patients, 3/7 (42.9 %) with a positive ADO challenge versus 1/74 (1.3 %) with a negative response, p = 0.0016 (relative risk: 31.7). The authors concluded that ADO challenge following atrial flutter ablation provoked transient or persistent resumption of conduction across the CTI in almost 9 % of patients and identified a subgroup at higher risk of flutter recurrence. Moreover, they state that it remains to be determined whether additional ablation guided by ADO testing during the index procedure may further improve procedural outcomes.

Sapp and colleagues (2013) stated that ablation of VT is sometimes unsuccessful when ablation lesions are of insufficient depth to reach arrhythmogenic substrate. These researchers reported the initial experience with the use of a catheter with an extendable/retractable irrigated needle at the tip capable of intra-myocardial mapping and ablation. Sequential consenting patients with recurrent VT underwent ablation with the use of a needle-tipped catheter. At target sites, the needle was advanced 7 to 9 mm into the myocardium, permitting pacing and recording. Infusion of saline/iodinated contrast mixture excluded perforation and ensured intra-myocardial deployment. Further infusion was delivered before and during temperature-controlled RF energy delivery through the needle. All 8 patients included (6 males; mean age of 54 years) with a mean left ventricular ejection fraction of 29 % were refractory to multiple anti-arrhythmic drugs, and 1 to 4 previous catheter ablation attempts (epicardial in 4) had failed. Patients had 1 to 7 (median of 2) VTs present or inducible; 2 were incessant. Some intra-myocardial VT mapping was possible in 7 patients. A mean of 22 (limits of 3 to 48) needle ablation lesions were applied in 8 patients. All patients had at least 1 VT terminated or rendered non-inducible. During a median of 12 months follow-up, 4 patients were free of recurrent VT, and 3 patients were improved, but had new VTs occur at some point during follow-up. Two died of the progression of pre-existing heart failure without recurrent VT. Complications included tamponade in 1 patient and heart block in 2 patients. The authors concluded that intra-myocardial infusion-needle catheter ablation is feasible and permits control of some VTs that have been refractory to conventional catheter ablation therapy, warranting further study.

Asakai et al (2015) noted that since the introduction of transcatheter ablation in the late 1980s, there has been significant technical development. With a very high success rate and low complication rate, ablation has now become the standard of care in children and adults. However, long-term data remain insufficient and the application of ablation therapy in small children is debatable. These investigators reviewed current treatment strategies and results in toddlers and infants. There has been improvement in success rate and complication rate for ablation in small children. The authors concluded that technological advancements in non-fluoroscopic electro-anatomical mapping systems (3D systems) have led to the reduction of radiation and have facilitated ablations in complex cases; however, long-term effects of ablation lesions in small children remain a potential concern.

Hakalahti et al (2015) performed a systematic review and meta-analysis of the available data to evaluate the safety and effectiveness of RFA versus AADs. Five databases were searched for RCTs
comparing RFA and AAD therapy as first-line treatment of AF in August 2014. A total of 3 studies with 491 patients with recurrent symptomatic AF were included. The patients were relatively young and the majority of them had paroxysmal AF (98.7\%) and no major co-morbidity. Radiofrequency catheter ablation was associated with significantly higher freedom from AF recurrence compared with AAD therapy [RR 0.63, 95 \% CI: 0.44 to 0.92, p = 0.02]. The difference in the rate of symptomatic AF recurrences was not statistically significant (RR 0.57, 95 \% CI: 0.30 to 1.08, p = 0.09). There was 1 procedure-related death and 7 tamponades with RFA, whereas symptomatic bradycardia was more frequent with AAD therapy. The authors concluded that RFA appeared to be more effective than medical therapy as first-line treatment of paroxysmal AF in relatively young and otherwise healthy patients, but may also cause more severe adverse effects. They stated that these findings support the use of RFA as first-line therapy in selected patients, who understand the benefits and risks of the procedure.

Verma et al (2015) noted that catheter ablation is less successful for persistent atrial fibrillation than for paroxysmal atrial fibrillation. Guidelines suggested that adjuvant substrate modification in addition to PVI is needed in persistent atrial fibrillation. These researchers randomly assigned 589 patients with persistent AF in a 1:4:4 ratio to ablation with PVI alone (67 patients), PVI plus ablation of electrograms showing complex fractionated activity (263 patients), or PVI plus additional linear ablation across the left atrial roof and mitral valve isthmus (259 patients). The duration of follow-up was 18 months. The primary end-point was freedom from any documented recurrence of AF lasting longer than 30 seconds after a single ablation procedure. Procedure time was significantly shorter for PVI alone than for the other 2 procedures (p < 0.001). After 18 months, 59 \% of patients assigned to PVI alone were free from recurrent AF, as compared with 49 \% of patients assigned to PVI plus complex electrogram ablation and 46 \% of patients assigned to PVI plus linear ablation (p = 0.15). There were also no significant differences among the 3 groups for the secondary end-points, including freedom from AF after 2 ablation procedures and freedom from any atrial arrhythmia. Complications included tamponade (3 patients), stroke or transient ischemic attack (3 patients), and atrio-esophageal fistula (1 patient). The authors concluded that among patients with persistent AF, they found no reduction in the rate of recurrent AF when either linear ablation or ablation of complex fractionated electrograms was performed in addition to PVI.

### CPT Codes / HCPCS Codes / ICD-10 Codes

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
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<tbody>
<tr>
<td>33250</td>
<td>Operative ablation of supraventricular arrhythmogenic focus or pathway (e.g., Wolff-Parkinson-White, atrioventricular node re-entry), tract(s) and/or focus (foci); without cardiopulmonary bypass or with cardiopulmonary bypass</td>
</tr>
<tr>
<td>33251</td>
<td>Operative ablation of supraventricular arrhythmogenic focus or pathway (e.g., Wolff-Parkinson-White, atrioventricular node re-entry), tract(s) and/or focus (foci); without cardiopulmonary bypass or with cardiopulmonary bypass</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</td>
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</table>
cardiopulmonary bypass (List separately in addition to code for primary procedure)

33261  Operative ablation of ventricular arrhythmogenic focus with cardiopulmonary bypass

+ 93613  Intracardiac electrophysiologic 3-dimensional mapping [for guiding radiofrequency ablation in the treatment of arrhythmias]

93650  Intracardiac catheter ablation of atroventricular node function, atroventricular conduction for creation of complete heart block, with or without temporary pacemaker placement [not covered for intra-myocardial infusion-needle catheter ablation for ventricular tachycardia]

93653  Comprehensive electrophysiologic evaluation including insertion and repositioning of multiple electrode catheters with induction or attempted induction of an arrhythmia with right atrial pacing and recording, right ventricular pacing and recording, His recording with intracardiac catheter ablation of arrhythmogenic focus; with treatment of supraventricular tachycardia by ablation of fast or slow atroventricular pathway, accessory atroventricular connection, cavo-tricuspid isthmus or other single atrial focus or source of atrial re-entry

93654  Comprehensive electrophysiologic evaluation including insertion and repositioning of multiple electrode catheters with induction or attempted induction of an arrhythmia with right atrial pacing and recording, right ventricular pacing and recording, His recording with intracardiac catheter ablation of arrhythmogenic focus; with treatment of ventricular tachycardia or focus of ventricular ectopy including intracardiac electrophysiologic 3D mapping, when performed, and left ventricular pacing and recording, when performed

93655  Intracardiac catheter ablation of a discrete mechanism of arrhythmia which is distinct from the primary ablated mechanism, including repeat diagnostic maneuvers, to treat a spontaneous or induced arrhythmia (List separately in addition to code for primary procedure)[not covered for intra-myocardial infusion-needle catheter ablation for ventricular tachycardia]

93656  Comprehensive electrophysiologic evaluation including transseptal catheterizations, insertion and repositioning of multiple electrode catheters with induction or attempted induction of an arrhythmia with atrial recording and pacing, when possible, right ventricular pacing and recording, His bundle recording with intracardiac catheter ablation of arrhythmogenic focus, with treatment of atrial fibrillation by ablation by pulmonary vein isolation

93657  Additional linear or focal intracardiac catheter ablation of the left or right atrium for treatment of atrial fibrillation remaining after completion of pulmonary vein isolation (List separately in addition to code for primary procedure)

Other HCPCS codes related to the CPB:

C1732  Catheter, Electrophysiology, diagnostic/ablation 3D or vector mapping

C1886  Catheter, extravascular tissue ablation, any modality (insertable)

ICD-10 codes covered if selection criteria are met:
| I44.30 - I44.7 | Bundle branch block |
| I45.0 - I45.4 | |
| I45.6 | Pre-excitation syndrome [Wolff-Parkinson-White syndrome] |
| I45.89 | Other specified conduction disorders |
| I47.0, I47.2 | Paroxysmal ventricular tachycardia, [unstable, rapid, multiple or polymorphic that cannot be localized by mapping - not covered] [benign non-sustained that does not cause symptoms - not covered] |
| I48.0 | Paroxysmal atrial fibrillation |
| I48.1 | Persistent atrial fibrillation |
| I49.3 | Ventricular premature depolarization |
| I49.8 - I49.9 | Other specified and unspecified cardiac arrhythmias [multifocal atrial tachycardia - not covered] |
| I97.710 - I97.711 | Intraoperative cardiac functional disturbances and postprocedural cardiac complications and disorders |
| I97.790 - I97.791 | |
| I97.88 - I97.89 | |
| Z86.74 | Personal history of sudden cardiac arrest |

**ICD-10 codes not covered for indications listed in the CPB:**

| I42.1 | Obstructive hypertrophic cardiomyopathy |
| I42.2 | Other hypertrophic cardiomyopathy |

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**The above policy is based on the following references:**


41. Bradley DJ, Shen WK. Atrioventricular junction ablation combined with either right ventricular pacing or cardiac resynchronization therapy for atrial fibrillation: The need for large-scale randomized trials. Heart Rhythm. 2007;4(2):224-232.


46. BlueCross BlueShield Association (BCBSA), Technology Evaluation Center (TEC). Pulmonary vein isolation for treatment of atrial fibrillation. TEC Assessment Program. Chicago, IL: BCBSA; May 2006;21(1).


66. Calkins H, Kuck KH, Cappato R, et al; Heart Rhythm Society Task Force on Catheter and Surgical Ablation of Atrial Fibrillation. 2012 HRS/EHRA/ECAS expert consensus statement on catheter and surgical ablation of atrial fibrillation: recommendations for patient selection, procedural techniques, patient management and follow-up, definitions, endpoints, and research trial design: a report of the Heart Rhythm Society (HRS) Task Force on Catheter and Surgical Ablation of Atrial Fibrillation. Developed in partnership with the European Heart Rhythm Association (EHRA), a registered branch of the European Society of Cardiology (ESC) and the European Cardiac Arrhythmia Society (ECAS); and in collaboration with the American College of Cardiology (ACC), American Heart Association (AHA), the Asia Pacific Heart Rhythm Society (APHRS), and the Society of Thoracic Surgeons (STS). Endorsed by the governing bodies of the American College of Cardiology Foundation, the American Heart Association, the European Cardiac Arrhythmia Society, the European Heart Rhythm Association, the Society of Thoracic Surgeons, the Asia Pacific Heart Rhythm Society, and the Heart Rhythm Society. Heart Rhythm. 2012;9(4):632-696.


80. Colín Lizalde Lde J. Supraventricular tachycardial ablation supported with an electroanatomical system. Arch Cardiol Mex. 2007;77 Suppl 4:139-143.


Amendment to
Aetna Clinical Policy Bulletin Number: 0165 Cardiac Catheter Ablation Procedures

There are no amendments for Medicaid.