

<b>BSC2.12</b>	<b>Catheter Ablation for Cardiac Arrhythmias</b>		
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<b>Section:</b>	2.0 Medicine	<b>Page:</b>	Page 1 of 25

## Policy Statement

- I. Catheter ablation may be considered **medically necessary** for the treatment of supraventricular tachyarrhythmias, for **any** of the following:
  - A. Treatment of atrial flutter
  - B. Treatment of focal atrial tachycardia
  - C. Treatment of paroxysmal supraventricular tachycardia due to accessory pathways
  - D. Treatment of paroxysmal supraventricular tachycardia due to atrioventricular nodal reentry tachycardia
- II. Catheter ablation using radiofrequency energy may be considered **medically necessary** for the treatment of chronic, recurrent, ventricular tachycardia that is refractory to implantable cardioverter defibrillator treatment and antiarrhythmic medications, and for which an identifiable arrhythmogenic focus can be identified.
- III. Catheter ablation for ventricular tachycardia storm (see Policy Guidelines section) may be considered **medically necessary** when pharmacologic treatment has been unsuccessful in controlling the arrhythmia.
- IV. Catheter ablation for all other ventricular arrhythmias is considered **investigational**.

**NOTE:** Refer to [Appendix A](#) to see the policy statement changes (if any) from the previous version.

## Policy Guidelines

Catheter ablation may be considered first-line treatment of the supraventricular tachyarrhythmias noted above; i.e., individuals do not need to have failed medical therapy to be considered for catheter ablation.

Permanent pacemaker implantation may be necessary following catheter ablation for supraventricular arrhythmias.

Ventricular tachycardia storm, also known as incessant ventricular tachycardia, is defined as at least 3 episodes of sustained ventricular tachycardia in a 24-hour period. Ventricular tachycardia storm is considered life-threatening and requires prompt attention and treatment.

This policy does not address catheter ablation for atrial fibrillation; refer to Blue Shield of California Medical Policy: Catheter Ablation as Treatment for Atrial Fibrillation if atrial fibrillation is a consideration.

## Description

Catheter ablation is a technique to eliminate cardiac arrhythmias by selectively destroying a portion of myocardium or conduction system tissue that contains the arrhythmogenic focus. A variety of energy sources can be used with catheter ablation, such as radiofrequency and/or cryotherapy.

## Related Policies

- Catheter Ablation as Treatment for Atrial Fibrillation
- Implantable Cardioverter Defibrillators

## Benefit Application

Benefit determinations should be based in all cases on the applicable contract language. To the extent there are any conflicts between these guidelines and the contract language, the contract language will control. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

Some state or federal mandates (e.g., Federal Employee Program [FEP]) prohibits plans from denying Food and Drug Administration (FDA)-approved technologies as investigational. In these instances, plans may have to consider the coverage eligibility of FDA-approved technologies on the basis of medical necessity alone.

## Regulatory Status

A very large number of percutaneous cardiac ablation catheters and catheter systems have been approved by the U.S. Food and Drug Administration (FDA) through the premarket approval process since 1994. FDA product code: LPB.

Also, various catheter-based electrosurgical cutting and coagulation accessories have been cleared for marketing by the FDA through the 510(k) process. For example, the Cardioblate<sup>®</sup> system (Medtronic) has been cleared for "[ablation] of cardiac tissue during general surgery using radiofrequency energy." FDA product code: OCL.

## Rationale

### Background

#### Catheter Ablation

Catheter ablation has been used as a treatment for cardiac arrhythmias for several decades. Radiofrequency energy is the most commonly used source, although other energy sources (e.g., cryoablation) have also been used. The technique treats supraventricular tachycardias by partially or fully ablating the atrioventricular node or accessory conduction pathways, thus ablating the arrhythmogenic focus. It controls idiopathic ventricular tachycardia or reentrant ventricular tachycardias by eliminating the focus.

Ablation is preceded by preprocedural imaging and mapping of the focus during electrophysiologic studies. Imaging and anatomic mapping systems recreate the 3-dimensional structure of the cardiac chambers. This imaging assists the electrophysiologist in defining the individual anatomy, locating the electroanatomic location of arrhythmogenic foci, and positioning the ablation catheter for delivery of radiofrequency energy. There are a variety of approaches to preprocedural imaging and mapping. Most commonly computed tomographic angiography and/or magnetic resonance imaging are used. Mapping can be done by an electroanatomic technique, by using multielectrode arrays, or by variations of these approaches.

Anticoagulation is indicated for some patients undergoing ablation. In general, ablations involving the right side of the heart for supraventricular arrhythmias do not require anticoagulation. Ablations in the left side of the heart are often combined with anticoagulation during and/or after the

procedure. There are no standardized guidelines for which patients should receive anticoagulation or for the duration of therapy.

### Cardiac Catheter Ablation Complications

Catheter ablation is invasive in that a catheter is passed into the heart via an arm or leg vein. The risks of catheter ablation vary with the specific type of procedure performed; risks are also affected by whether there are underlying structural abnormalities of the heart. Various complications have been documented, which include the following:

- Vascular injury. Injury can occur to the peripheral vessels at the site of vascular access, with resulting hemorrhage, arteriovenous fistula, and/or pseudoaneurysm formation. Venous injury may lead to deep venous thrombosis, with the attendant risk of pulmonary embolism. Significant vascular injury has been estimated to occur in approximately 2% of ablation procedures.
- Cardiac tamponade. Perforation of the myocardium can lead to bleeding into the pericardial space and cardiac tamponade. This complication is estimated to occur in approximately 1% of ablation procedures and may require pericardiocentesis for treatment.
- Myocardial ischemia/infarction. Ischemia or infarction can result from damage to the coronary arteries during the procedure or from demand ischemia as a result of the procedure. The rate of these complications is not well characterized.
- Thromboembolism. Destruction of tissue by radiofrequency energy promotes thrombus formation. Thromboembolism following ablation most commonly leads to stroke or transient ischemic attack. The estimated incidence of stroke or transient ischemic attack following catheter ablation is 1.3%.
- Heart failure. Heart failure can be precipitated by “stunning” of myocardium following ablation and/or by the saline administration required during the procedure. Patients who are at risk for this complication are mostly those with preexisting left ventricular dysfunction. Patients undergoing large ablations of the left ventricle are at greatest risk.
- Radiation exposure. In any ablation procedure using radiofrequency energy, the patient is exposed to radiation from fluoroscopy. Systems intended to reduce radiation exposure (e.g., electroanatomic mapping, remote navigation systems) are available.

### Literature Review

Evidence reviews assess the clinical evidence to determine whether the use of a technology improves the net health outcome. Broadly defined, health outcomes are length of life, quality of life, and ability to function—including benefits and harms. Every clinical condition has specific outcomes that are important to patients and to managing the course of that condition. Validated outcome measures are necessary to ascertain whether a condition improves or worsens; and whether the magnitude of that change is clinically significant. The net health outcome is a balance of benefits and harms.

To assess whether the evidence is sufficient to draw conclusions about the net health outcome of a technology, 2 domains are examined: the relevance and the quality and credibility. To be relevant, studies must represent one or more intended clinical use of the technology in the intended population and compare an effective and appropriate alternative at a comparable intensity. For some conditions, the alternative will be supportive care or surveillance. The quality and credibility of the evidence depend on study design and conduct, minimizing bias and confounding that can generate incorrect findings. The randomized controlled trial (RCT) is preferred to assess efficacy; however, in some circumstances, nonrandomized studies may be adequate. RCTs are rarely large enough or long enough to capture less common adverse events and long-term effects. Other types of studies can be used for these purposes and to assess generalizability to broader clinical populations and settings of clinical practice.

## Supraventricular Arrhythmias

### Paroxysmal Supraventricular Tachycardia

Paroxysmal supraventricular tachycardia (PSVT) arises from abnormal conduction through the atrioventricular (AV) node or through accessory conduction pathways that bypass the AV node. There are several subtypes of PSVT, the most common being atrioventricular nodal reentrant tachycardia (AVNRT).<sup>1</sup> Ablations for PSVT can usually be done in the right atrium, thus reducing the risk of entering the left atrium through transseptal puncture. Because these ablations are very focused and confined to the right side of the heart, complications are less than with other ablations. The main complication of ablation is high-grade AV block that may require placement of a pacemaker.

Evidence on the efficacy of catheter ablation for PSVT consists of numerous case series and uncontrolled trials. No large-scale RCTs have compared ablation with placebo or alternative treatments. The available evidence has established that catheter ablation is associated with high rates of success in abolishing PSVT, with low rates of AV block. For example, the North American Society of Pacing and Electrophysiology prospective catheter ablation registry reported on 1197 patients undergoing ablation for AVNRT.<sup>1</sup> Success in eliminating the arrhythmia was reported in 96.1% of patients, with a 1% incidence of second- or third-degree AV block. The recurrence rate was estimated to be between 3% and 7%. Case series in pediatric patients have also demonstrated high rates of procedural success: eg, 91% in a series of 318 children treated with radiofrequency ablation (RFA) for supraventricular arrhythmias,<sup>2</sup> and 90% in a series of 140 children treated with RFA for permanent junctional reciprocating tachycardia.<sup>3</sup>

Several RCTs have compared RFA with cryoablation for PSVT due to AVNRT. Deisenhofer et al (2010) randomized 509 patients with AVNRT to cryoablation (n=251) or RFA (n=258).<sup>4</sup> Patients in both groups had very high rates of immediate ablation success. Immediate success rates were slightly higher in the cryoablation group (98.4% vs 96.8%), but this difference was not statistically significant. At 6-month follow-up, more patients in the cryoablation group reached the primary composite end point of immediate ablation failure, permanent AV block, and recurrent AVNRT (12.6% vs 6.3%, p=0.018). This difference in the composite outcome was primarily driven by a higher rate of recurrent AVNRT in the cryoablation group (9.4% vs 4.4%, p=0.029). Rodriguez-Entem et al (2013) reported on results from an RCT that included 119 patients with AVNRT who were assigned to cryoablation (n=60) or RFA (n=59).<sup>5</sup> Rates of acute procedural success were again high in both groups (98% in the cryoablation group vs 100% in the RFA group). Over longer follow-up (mean, 256.6 days), recurrent AVNRT was more common in the cryoablation group (15% vs 3.4%, p=0.03). One patient in the RFA group had permanent AV block vs no patients in the cryoablation group.

A multicenter RCT reported by Casella et al (2016) compared minimally fluoroscopic catheter RFA with conventional fluoroscopy-guided ablation for supraventricular tachycardias (SVTs) in 262 patients (mean age, 36 years) undergoing electrophysiology studies for SVT.<sup>6</sup> The mean follow-up was 12 months. The acute success rate was 99% in both groups, with a 1.1% complication rate. The long-term success rate was 97% in the minimally fluoroscopic group and 94% in the conventional group. The minimally fluoroscopic group had a significantly lower radiation dose (0 mSv [interquartile range (IQR)], 0-0.08 mSv] vs 8.87 mSv [IQR, 3.67-22.01 mSv]; p<0.001) and total fluoroscopy time (0 seconds [IQR, 0-12] vs 859 seconds [IQR, 545-1346 seconds]; p<0.001). X-ray was not used in 72% of patients in the minimally fluoroscopic group.

Ablation of PSVT due to accessory pathways has shown similar or slightly lower success rates. Most clinical series and registries have reported success rates in the 85% to 100% range. In a survey covering 6065 patients undergoing ablation during the period of 1997 to 2002, Morady (2004) reported a long-term success rate for accessory pathway ablation of 98%.<sup>7</sup> Repeat procedures were necessary in 2.2% of cases, and a serious complication (ie, tamponade, AV block, coronary artery injury, retroperitoneal hemorrhage, stroke) occurred in 0.6% of patients. The 1995 North American Society of Pacing and Electrophysiology survey included 5427 patients undergoing accessory pathway ablation. Serious complications occurred in 1.8% (99/5427) of patients, with a mortality rate

of 0.08% (4/5427). As part of the evidence review supporting the 2016 American College of Cardiology, American Heart Association, and Heart Rhythm Society guidelines on the management of adults with SVT,<sup>8</sup> Al-Khatib et al (2016) conducted a systematic review (2016)<sup>9</sup> to answer 4 questions, one of which is relevant to this review: "What are the efficacy and effectiveness of invasive EP [electrophysiology] study with catheter ablation of the accessory pathway as appropriate vs noninvasive tests with treatment (including observation) or no testing/ablation as appropriate for preventing arrhythmic events (including sudden cardiac death) and improving outcomes in patients with asymptomatic pre-excitation?" Reviewers found a 2003 dual-design RCT/observational study relevant to this question.<sup>10</sup> The RCT component compared ablation with no-ablation in 72 patients who were asymptomatic with ventricular pre-excitation documented by 12-lead electrocardiograph and inducible arrhythmia on electrophysiology study; patients were no older than 35 years of age. The median follow-up was 27 months during which 2 (5%) of the 37 patients in the ablation group had regular SVT compared with 21 (60%) of the 35 patients in the no-ablation group. The incidence rates of arrhythmic events were 7% in the ablation group compared with 77% in the no-ablation group (relative risk reduction, 0.08; 95% confidence interval [CI], 0.02 to 0.33;  $p < 0.001$ ).

### **Atrial Flutter**

#### ***Atrial Flutter Associated with Cavotricuspid Isthmus***

Atrial flutter usually arises from reentrant circuits, the most common of which is associated with the cavotricuspid isthmus. Success rates following ablation have varied, partly because of the evolution of the technique and partly because of varying definitions of recurrence. In a summary of studies that used current techniques and a stringent definition of treatment success, success rates of 90% to 100% were estimated.<sup>1</sup> One small RCT compared catheter ablation with medications for this arrhythmia. After a mean follow-up of 21 months, 80% of patients treated with ablation remained in sinus rhythm compared with only 36% of patients treated with medications.<sup>11</sup>

In a survey of 7071 procedures for isthmus-associated atrial flutter (previously discussed), Morady (2004) reported a success rate in preventing recurrent atrial flutter of 97%.<sup>7</sup> Repeat procedures were required in 4% of patients. Serious complications were reported in 0.4% of patients, the most common of which was AV block. Other reported complications included injury to the coronary arteries and ventricular arrhythmias. Bastani et al (2013) reported on results of an RCT comparing cryoablation with RFA in 153 patients with atrial flutter associated with the cavotricuspid isthmus.<sup>12</sup> Acute and 6-month success rates were similar for the cryoablation and RFA groups, with less procedure-related pain in the cryoablation group. Chen et al (2015) reported on results of a meta-analysis evaluating the efficacy and safety of cryoablation vs RFA for patients with cavotricuspid valve isthmus-dependent atrial flutter.<sup>13</sup> Seven RCTs (total N=496 participants) published between 1986 and 2014 were included in the review. Acute success was achieved in 85.4% in the cryotherapy group vs 92.7% in the RFA group (relative risk, 0.93; 95% CI, 0.85 to 1.02;  $p = 0.14$ ) and long-term success was reported in 91.8% vs 96.6% (relative risk, 0.95; 95% CI, 0.91 to 1.01;  $p = 0.08$ ). The fluoroscopy time was nonsignificantly shorter (weighted mean difference, -2.83 seconds; 95% CI, -8.06 to 2.40 seconds;  $p = 0.29$ ) in cryoablation while the procedure time was significantly longer (weighted mean difference, 25.95 seconds; 95% CI, 5.91 to 45.99 seconds;  $p = 0.01$ ). Pain perception during ablation was considerably lower in the cryoablation group than in the RFA group (standardized mean difference, -2.36; 95% CI, -3.30 to -1.41;  $p < 0.001$ ).

#### ***Atrial Flutter Not Associated with Cavotricuspid Isthmus***

Atrial flutter not associated with the cavotricuspid isthmus is less common, and there is less evidence on efficacy. In a combined analysis of 6 studies (total N=134 patients), success rates in abolishing atrial flutter were 50% to 88% after an average follow-up of 2 years.<sup>1</sup> Expert opinion has estimated that, with the current availability of 3-dimensional mapping systems, success for non-isthmus-dependent atrial flutter is expected to be at least 90%.<sup>7</sup>

### **Focal Atrial Tachycardia**

Focal atrial tachycardia usually arises from an abnormal automatic focus or micro-reentry circuits in the right atrium. Ablation involves identification of the abnormal trigger by mapping studies, followed by focused ablation of the abnormal area.

Atrial tachycardias are relatively uncommon; as a result, the evidence on the efficacy of catheter ablation is limited. Pooled data from 514 patients undergoing ablation have suggested a success rate of 86%, with a recurrence rate of 8%.<sup>1</sup> Serious complications occurred in 1% to 2% of patients, consisting of cardiac perforation, phrenic nerve damage, and sinus node dysfunction. In another combined analysis of 7 studies (total N=112 patients), the success rate for ablation of focal atrial tachycardia was approximately 90%, with late recurrences reported in 7% of patients.<sup>7</sup>

In a retrospective multicenter study of 249 pediatric patients with focal atrial tachycardia, Kang et al (2014) reported on 134 patients who underwent catheter ablation for a total of 167 procedures, including 69 (28% of total) for catheter ablation as a primary management strategy.<sup>3</sup> Ablation therapy was successful in 109 (81%) of 134 patients.

### **Section Summary: Supraventricular Arrhythmias**

For patients with supraventricular arrhythmias and identifiable arrhythmogenic foci, numerous uncontrolled studies have reported high success rates with low adverse event rates. Success in eliminating PSVT following catheter ablation is likely to be in the range of 95% or higher, and success in eliminating atrial flutter is likely to be in the 90% to 100% range. Several RCTs have evaluated different ablation techniques, with similar rates of PSVT elimination and higher rates of recurrence for cryoablation vs RFA. There were no significant differences in the rates of permanent AV block, but rates of this complication were very low in both groups, and small differences cannot be excluded. There is less evidence of focal atrial tachycardia, with lower reported success rates. For patients who desire to avoid medications, catheter ablation is a reasonable first-line alternative treatment for these supraventricular arrhythmias.

### **Ventricular Arrhythmias**

#### **Ventricular Tachycardia due to Structural Heart Disease**

Ventricular tachycardia (VT) most commonly occurs in the setting of underlying structural heart disease. VT in a patient with structural heart disease is usually precipitated by scar tissue in the left ventricle.<sup>14</sup> Scar tissue can arise as a result of myocardial infarction (MI) or from fibrosis of myocardium that occurs with nonischemic cardiomyopathy. Ablation in patients with structural heart disease is more difficult than for patients with idiopathic VT, for several reasons: larger areas of ablation are typically required; there are often multiple areas that require ablation; and patients with structural heart disease are at higher risk for complications at baseline.

Evidence on the efficacy of ablation for these patients comes largely from case series and a few controlled studies.

#### ***Systematic Reviews***

Mallidi et al (2011) performed a meta-analysis of controlled studies of catheter ablation for ventricular arrhythmias.<sup>15</sup> Five controlled studies (total N=457 patients) were identified. Four were RCTs, although two were unpublished, and the fifth was a small non-RCT from Japan. There was a decreased overall risk of VT recurrence for patients undergoing catheter ablation compared with treatment without ablation (odds ratio [OR], 0.62; 95% CI, 0.51 to 0.76). In the 2 unpublished RCTs, the absolute reduction in VT recurrence was reported to be 26% and 13%, respectively, although statistical testing for these differences was not reported. Combined analysis of complications concluded the following rates of adverse events: death (1%), stroke (1%), cardiac perforation (1%), and complete heart block (1.6%).

Santangeli et al (2016) published a systematic review of the comparative effectiveness of catheter ablation and antiarrhythmic drugs for the prevention of recurrent VT in patients with implantable

cardioverter defibrillators (ICDs).<sup>16</sup> Reviewers searched RCTs evaluating antiarrhythmic drugs or catheter ablation vs medical management published before October 2015. They included 14 trials in the meta-analysis: 8 trials (2268 patients) evaluated antiarrhythmic drugs, and 6 trials (427 patients) evaluated catheter ablation. Three catheter ablation trials included in Mallidi (2011) were also in the Santangeli (2016) review. No direct comparisons of antiarrhythmic drugs with catheter ablation were included; the search for this review occurred before publication of the VANISH trial (described below). Both catheter ablation (OR=0.45; 95% CI, 0.28 to 0.71,  $p=0.001$ ) and antiarrhythmic drugs (OR=0.66, 95% CI, 0.44 to 0.97;  $p=0.037$ ) were associated with a significant reduction in inappropriate ICD interventions. An indirect comparison between catheter ablation and antiarrhythmic drugs found no significant difference between the strategies in the reduction of risk of recurrent VT (ratio of OR=0.58; 95% CI, 0.26 to 1.27;  $p=0.174$ ) or all-cause mortality (ratio of OR=0.58; 95% CI, 0.24 to 1.42;  $p=0.234$ ).

### **Randomized Controlled Trials**

#### *Catheter Ablation Plus ICD vs ICD Alone*

Two RCTs have evaluated catheter ablation plus ICD vs ICD alone for patients with VT and previous MI. These trials were designed to evaluate whether catheter ablation can reduce the number of ICD discharges. A third RCT compared catheter ablation plus ICD with ICD alone in patients who had ventricular arrhythmias and coronary artery disease.

The SMASH-VT study (2007) randomized 128 patients with VT or ventricular fibrillation (VF) and a prior MI who were not receiving antiarrhythmic medications.<sup>17</sup> The mean follow-up was 22.5 months. The primary end point was survival free from any appropriate ICD therapy (shocks or antitachycardia pacing). Major complications related to catheter ablation occurred in 4.7% (3/64) patients. One patient had a pericardial effusion that did not require intervention, one had worsening heart failure that required prolonged hospitalization, and another had a deep vein thrombosis that required anticoagulation. The primary end point was reached by 12% (8/64) of patients in the ablation group compared with 33% (21/64) in the defibrillator alone group (hazard ratio [HR], 0.31; 95% CI, 0.13 to 0.76;  $p=0.01$ ). There were fewer deaths in the ablation group (3/64 vs 6/64, respectively), but this difference was not statistically significant ( $p=0.29$ ). There was no difference in New York Heart Association functional class at the end of follow-up.

The Ventricular Tachycardia Ablation in Coronary Heart Disease (VTACH) trial randomized 110 patients from 16 centers in Europe who had stable VT, previous MI, and a left ventricular ejection fraction less than 50% to catheter ablation plus ICD or ICD alone.<sup>18</sup> Antiarrhythmic medications were allowed at the discretion of the treating clinician. Of 52 patients assigned to ablation, 7 did not undergo the procedure. Twelve of 55 patients in the ICD alone group crossed over to the ablation group. All analyses were performed using intention-to-treat analysis. Patients were followed for a mean of 22.5 months for the primary end point (first recurrence of VT or VF). Time to the primary outcome was 18.6 months in the ablation group compared with 5.9 months in the ICD alone group ( $p=0.045$ ). By Kaplan-Meier analysis, 59% of patients in the ablation group, compared with 40% in the ICD alone group, were free of any VT or fibrillation event at 12-month follow-up. Quality-of-life data, measured by the 36-Item Short-Form Health Survey, were available for a subset of patients (n varied between 20 and 30 in each group). There were no significant between-group differences for any quality-of-life measures. There was a significant difference in the secondary outcome (hospitalizations) in favor of the ablation group (HR=0.55; 95% CI, 0.30 to 0.99;  $p=0.04$ ). There were no differences in the other secondary outcomes of death, VT storm, or syncope.

The 2017 industry-sponsored multicenter substrate modification study randomized 111 patients with unstable ventricular arrhythmias and coronary artery disease to prophylactic catheter ablation plus ICD implantation or ICD ablation alone.<sup>19</sup> Of the 54 modified intention-to-treat patients randomized to catheter ablation, 48 underwent the procedure, and ablation success was achieved in 45. The primary end point was the time to first recurrence of VT and VF, which was obtained in 25 patients in both the ablation group and ICD only group. Kaplan-Meier analysis showed no significant difference in the primary outcome. The 2-year estimate of freedom from VT and VF was 49.0% (95% CI, 33.3%

to 62.9%) in the ablation group and 52.4% (95% CI, 36.7% to 65.9%) in the ICD only group. There were no significant differences between groups in any secondary outcome measures for time to the first event. However, analysis of repeat events showed a significant advantage of catheter ablation for most outcome measures.

### ***Catheter Ablation Plus ICD vs Medication Plus ICD***

Two RCTs compared catheter ablation with antiarrhythmic medication for patients with VT and an ICD. Al-Khatib et al (2015) published results of a pilot RCT comparing early catheter ablation with antiarrhythmic medication therapy among patients with ischemic heart disease, an ICD, and a history of at least 1 ICD shock or at least 3 antitachycardia pacing therapies for VT.<sup>20</sup> Twenty-seven patients were randomized to antiarrhythmic medication (n=14) or catheter ablation (n=13); enrollment was terminated prematurely. Two deaths occurred in each group during the 6-month follow-up. Fourteen patients had recurrent VT—8 (62%) in the ablation arm and 6 (43%) in the antiarrhythmic medication arm. Three patients developed heart failure—2 (15%) in the ablation arm and 1 (7%) in the antiarrhythmic medication arm. Twelve patients were hospitalized for VT—5 (46%) in the ablation arm and 7 (50%) in the antiarrhythmic medication arm. Three (23%) patients in the ablation arm and 5 (36%) in the antiarrhythmic medication arm developed serious adverse events. Statistical comparisons between groups were not presented, although the authors indicated that none of the end points differed statistically between arms.

Results from the Ventricular Tachycardia Ablation versus Escalated Antiarrhythmic Drug Therapy in Ischemic Heart Disease (VANISH) trial were reported by Sapp et al (2016).<sup>21</sup> VANISH was a multicenter RCT enrolling patients with ischemic cardiomyopathy, an ICD, and VT despite the use of antiarrhythmic drugs. Patients were randomized to catheter ablation (n=132) with the continuation of baseline antiarrhythmic medications or escalated antiarrhythmic drug therapy (n=127). The primary outcome was a composite of death, VT storm, or appropriate ICD shock. The analysis was intention-to-treat. The mean follow-up was 27.9 months. Seventy-eight (59.1%) of 132 patients in the ablation group and 87 (68.5%) of 127 in the escalated therapy group experienced the primary outcome (HR=0.72; 95% CI, 0.53 to 0.98; p=0.04). There was no difference in mortality; 36 (27.3%) patients in the ablation group and 35 (27.6%) in the escalated therapy group died (HR=0.96; 95% CI, 0.60 to 1.53; p=0.86). The difference in the primary outcome was driven by differences in rates of appropriate shocks and episodes of VT storm. VT storm occurred in 32 (24.2%) patients in the ablation group and 42 (33.1%) patients in the escalated therapy group (HR=0.66; 95% CI, 0.42 to 1.05; p=0.08). Treatment-related adverse events were more frequent (51 vs 22; p=0.002) in the escalated therapy group.

### ***Nonrandomized Comparative Studies***

A nonrandomized, comparative study by Bunch et al (2014) evaluated outcomes for 102 patients with VT due to structural heart disease who underwent catheter ablation for recurrent ICD shocks; this group was compared with 2088 patients with ICDs and no history of appropriate shocks and 817 patients with ICDs and a history of appropriate shocks for VT or VF.<sup>22</sup> Kaplan-Meier survival curves demonstrated that patients who had appropriate shocks but who did not undergo catheter ablation had consistently higher mortality rates than both other groups (p<0.001).

Tilz et al (2018) conducted a retrospective analysis of the German Multicenter Ablation Registry to determine predictors of mortality and VT recurrence after treatment with catheter ablation.<sup>23</sup> Of 334 patients, 118 (35.3%) had structurally normal hearts, and 216 (64.7%) had structural heart disease, of which 74.5% had ischemic heart disease. At a follow-up of 21.0 months, 42 (12.8%) patients had died, and 102 (36.7%) experienced nonfatal VT recurrence. The strongest predictors of 2-year mortality included age greater than 60 (adjusted HR=5.56; 95% CI, 2.08 to 14.86), incessant VT (adjusted HR=2.99; 95% CI, 1.27 to 7.07), and procedural failure (adjusted HR=2.99; 95% CI, 1.27 to 7.07); other predictors included a left ventricular ejection fraction of less than 30%, use of class I antiarrhythmic drugs, and use of class III antiarrhythmic drugs at discharge (adjusted HR=2.16; 95% CI, 1.12 to 4.57). The only significant predictor of nonfatal VT recurrence was a procedural failure (OR=4.76; 95% CI,



1.78 to 12.75). Study limitations included operator inexperience, heterogeneous populations, and insufficient baseline data.

### ***Noncomparative Studies***

Several prospective, multicenter cohort studies have been published. The largest multicenter study is the Multicentre Thermocool Ventricular Tachycardia Ablation Trial, which enrolled 231 patients with recurrent VT and prior MI from 18 centers.<sup>24</sup> These patients had a high burden of VT (median, 11 episodes in the prior 6 months), and 70% had previously failed treatment with amiodarone. Mortality within 7 days of the procedure was 3% (7/231); four of these deaths occurred in the electrophysiology lab at the time of the procedure. The primary end point (freedom from recurrent incessant or intermittent VT) was achieved by 53% (123/231) of patients. Mortality at 1-year follow-up was 18%, with approximately one-third of the deaths attributed to arrhythmias.

Calkins et al (2000) enrolled 146 patients from 18 clinical centers who had stable VT, ischemic heart disease, an ICD, and who had failed at least 2 prior antiarrhythmic medications.<sup>25</sup> Acute procedural success was achieved in 75% of patients. After a mean follow-up of 243 days, 46% of patients experienced a recurrence of any tachyarrhythmia. Major complications arose in 8% (12/146) of patients, four of these complications led to death (periprocedural mortality rate, 2.7%).

As reported by Tanner et al (2010), the Euro-VT study enrolled 63 patients from 8 centers in Europe with sustained VT and prior MI who were refractory to previous drug and/or device therapy.<sup>26</sup> Two-thirds of the patients had prior ICD implantation. Procedural success was achieved in 81% of patients. Freedom from VT at 12 months was approximately 45% by Kaplan-Meier analysis. During a mean follow-up of 12 months, 49% (31/63) of patients had VT recurrence. There were no deaths within 30 days of the procedure.

### ***Section Summary: Ventricular Tachycardia due to Structural Heart Disease***

A number of RCTs have compared catheter ablation with usual care, and 1 RCT has directly compared escalation of antiarrhythmic medications with catheter ablation in patients who had VTs and an automatic ICD. Studies reported that procedural success was high and that catheter ablation was successful in reducing the number of VT episodes and the number of automatic ICD shocks. The rate of serious procedural adverse events was low in these trials. The more recent VANISH trial found a significantly lower rate of a composite of death, VT storm, and appropriate ICD shock among patients undergoing catheter ablation vs those receiving an escalation in antiarrhythmic drug therapy. Patients in this trial had ischemic cardiomyopathy, an ICD, and VT despite antiarrhythmic drug therapy. A pilot RCT demonstrated no significant outcome differences between catheter ablation and medical management for VT but may have been underpowered to detect a difference between groups. Observational studies have corroborated a decrease in VT following catheter ablation in similar patient populations. This evidence is sufficient to conclude that catheter ablation improves outcomes for patients with VT and an automatic ICD when the frequency of VT episodes and automatic ICD shocks are not adequately controlled by medications.

### **Idiopathic VT**

Idiopathic VT refers to tachycardia in the absence of demonstrable heart disease. It most commonly arises from the right ventricular outflow tract, although it sometimes arises from the left ventricular outflow tract or other cardiac structures.<sup>14</sup> Idiopathic VT is relatively benign compared with other forms of VT; it is usually well-tolerated, and sudden death is rare.

Because idiopathic VT is an uncommon disorder, there is limited evidence (small clinical series) on the efficacy of catheter ablation. In a series of 48 patients, Rodriguez et al (1997) reported that catheter ablation successfully eliminated the VT focus in 83% (29/35) of patients with right ventricular outflow tract VT and 92% (12/13) of patients with left ventricular outflow tract VT.<sup>27</sup> In other small series, ablation successfully eliminated the VT focus in 54% to 92% of patients.<sup>28-31</sup> Recurrence rates of VT at variable durations of follow-up ranged from 0% to 14%.

Another series of 44 patients was reported by Pytkowski et al (2012).<sup>32</sup> This series included patients with VT (n=23) and with frequent premature ventricular contractions (n=21) originating from the right ventricular outflow tract. All patients underwent successful ablation and were followed up at 3 months. The primary outcome was an improvement in quality of life, as measured by a change in the 36-Item Short-Form Health Survey score. A statistically significant improvement was reported on 6 of 8 Health Survey domains. However, there were no significant improvements in the Physical Component or the Mental Component Summary scores.

Kawakami et al (2018) reported retrospectively on 80 patients with idiopathic left VT who are sensitive to verapamil, 51 of whom underwent radiofrequency ablation; patients were followed for a mean of 10 years.<sup>33</sup> VT resolution was observed in 90% (46/51) of patients who underwent ablation and in 55% (16/29) of patients who did not. The mechanism by which idiopathic left VT spontaneously resolved is unclear. Limitations included a significant dropout rate due to loss of follow-up or protocol violations.

A retrospective series with long-term follow-up by Kumar et al (2016) assessed VT ablation results in patients without structural heart disease.<sup>34</sup> Acute complete success was achieved in 79% of this patient population, with a major complications rate of 3.7%. With a median follow-up of 6 years, ventricular arrhythmia-free survival was 77%, and overall survival was 100%.

### ***Section Summary: Idiopathic VT***

There is limited evidence on the treatment of patients with structurally normal hearts and idiopathic VT. Small case series have reported high success rates in eliminating the VT focus of arrhythmia, with low rates of serious adverse events and relatively low rates of recurrence. While this evidence suggests that there is a benefit to catheter ablation for this population, it is inconclusive due to the small numbers of patients and the lack of controlled trials.

### **Incessant VT (Storm)**

Incessant VT, or “ventricular tachycardia storm,” refers to tachycardia that occurs more than 3 times in a 24-hour period, often in association with an acute cardiac event such as MI. VT storm is a potentially life-threatening situation and requires rapid treatment and control. The evidence base for this indication consists of small case series describing outcomes after treatment with catheter ablation.

A systematic review of case series was published by Nayyar et al (2013), which included 39 reports (total N=471 patients).<sup>35</sup> Successful termination of all ventricular arrhythmias was achieved in 72% of cases (95% CI, 71% to 89%), and treatment failure occurred in 9% (95% CI, 3% to 10%). Three (0.6%) deaths were associated with the procedure, and recurrence of VT storm was 6%. During a mean follow-up of 61 weeks, 17% of patients died, with approximately one-quarter of all deaths attributed to arrhythmias. The risk of death was approximately 4 times higher for patients with a failed procedure than for patients with a successful procedure.

One of the larger series (N=95) of patients with an ICD and drug-refractory VT storm was reported by Carbucicchio et al (2008).<sup>36</sup> Catheter ablation was successful in acutely suppressing VT storm in all patients, although some required a second or a third procedure to achieve control. All VTs were eliminated in 89% of patients. After a mean follow-up of 22 months, 92% (87/95) of patients remained free of VT storm; 12% (11/95) patients died of cardiac causes.

Kumar et al (2017) reported on a consecutive series of 287 patients (186 ischemic, 101 nonischemic) with VT storm and 267 patients (368 ischemic, 268 nonischemic) with a non-storm presentation who had failed antiarrhythmic drugs and underwent catheter ablation.<sup>37</sup> Mean follow-up was 51 months. In the subgroup of VT storm patients with ischemic cardiomyopathy, VT-free survival was 51%, and

survival free of death or transplant was 75%. In the subgroup of storm patients with nonischemic cardiomyopathy, VT-free survival was 36%, and survival free of death or transplant was 72%.

Other smaller series have also reported similar outcomes of ablation in VT storm.<sup>38-40</sup> For example, Arya et al (2010) reported on 30 patients with ischemic heart disease and VT storm who were treated with catheter ablation.<sup>38</sup> Acute success, defined as suppression of all VT, was achieved in 80% of patients. After a mean follow-up of 7.8 months, 70% (21/30) of patients remained free of VT. No serious complications related to ablation were reported.

Mussigbrodt et al (2015) reported on outcomes after ablation for VT storm in 28 patients with arrhythmogenic right ventricular cardiomyopathy who had ICDs in place.<sup>40</sup> Forty-eight ablation procedures, including 6 epicardial procedures, were conducted. Three (6.3%) major periprocedural complications occurred, including 1 pericardial effusion due to right ventricular perforation, which required emergency surgery, and 2 massive pulmonary thromboembolisms, 1 fatal. During a mean follow-up of 18.7 months (range, 1-64 months), 15 (53.5%) patients had no recurrence of VT based on regular ICD interrogations and clinical follow-up and received no ICD therapy.

### ***Section Summary: Incessant VT (Storm)***

Case series have reported high procedural success rates for catheter ablation in VT storm. Serious complications occur at reasonably low rates, and mortality from the procedure was reported to be 0.6% in a meta-analysis of case series. Because of the emergent nature of this condition, RCTs are not expected to be performed. Also, there are no other available treatment options for patients with VT storm who fail pharmacologic interventions, so catheter ablation for this population may be a treatment option.

## **Summary of Evidence**

### **Supraventricular Arrhythmia**

For individuals who have supraventricular arrhythmias who receive catheter ablation, the evidence includes an RCT and numerous case series and uncontrolled trials. Relevant outcomes are overall survival, symptoms, change in disease status, morbid events, medication use, and treatment-related morbidity. Clinical series of paroxysmal supraventricular tachycardia have reported very high success rates at well over 90%. Serious complications, mainly atrioventricular block requiring pacemaker insertion, occur in approximately 1% of patients. High success rates are also reported for atrial flutter and focal atrial tachycardia. There are few comparative or trial data. The RCT assessing catheter ablation of the accessory pathway confirmed that incidence of arrhythmic events is greatly reduced with catheter ablation. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

### **Ventricular Arrhythmia**

For individuals with drug- and ICD-refractory VT due to structural heart disease who receive catheter ablation, the evidence includes RCTs and systematic reviews of RCTs. Relevant outcomes are overall survival, symptoms, change in disease status, morbid events, medication use, and treatment-related morbidity. Across 10 individual RCTs that compared catheter ablation with usual care (medical management) and 1 RCT that directly compared escalation of antiarrhythmic medications with catheter ablation in patients who had VTs and an automatic ICD, the evidence has shown that procedural success is 80% to 90%, and that catheter ablation is successful at reducing the number of VT episodes by about 30%. The evidence has further shown that catheter ablation is associated with approximately a 50% reduction in inappropriate ICD interventions compared with usual medical management alone. The rate of serious procedural adverse events is low. Late recurrences do occur, but most patients treated with ablation remain free of VT at 1- to 2-year follow-ups and 40% to 50% remain VT-free after 6 years of follow-up. The trial directly comparing catheter ablation with the escalation of medication found a 28% lower rate of a composite of death, VT storm, and appropriate ICD shock among patients undergoing catheter ablation vs those receiving an escalation in

antiarrhythmic drug therapy. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

For individuals who have idiopathic VT refractory to drug therapy and ICD placement who receive catheter ablation, the evidence includes a few case series. Relevant outcomes are overall survival, symptoms, change in disease status, morbid events, medication use, and treatment-related morbidity. There are no comparative or trial data and, given the rarity of the disease, such RCTs are unlikely. Case series have reported high success rates and low adverse event rates with catheter ablation. However, the body of literature is small. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who have VT storm who have failed pharmacologic treatment who receive catheter ablation, the evidence includes a few case series. Relevant outcomes are overall survival, symptoms, change in disease status, morbid events, medication use, and treatment-related morbidity. Serious complications have been reported at reasonably low rates, and mortality from the procedure was reported to be 0.6% in a meta-analysis of case series. There are no comparative or trial data. Because of the emergent nature of this condition, RCTs are not expected to be performed. In these situations, morbidity and mortality are expected to be extremely high in patients who have failed pharmacologic therapy; therefore, catheter ablation is expected to reduce morbidity and mortality. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

### Supplemental Information

#### Clinical Input from Physician Specialty Societies and Academic Medical Centers

While the various physician specialty societies and academic medical centers may collaborate with and make recommendations during this process, through the provision of appropriate reviewers, input received does not represent an endorsement or position statement by the physician specialty societies or academic medical centers, unless otherwise noted.

In response to requests from Blue Cross Blue Shield Association, input was received in 2012. There was uniform agreement on the treatment of supraventricular arrhythmias and general agreement for treatment of ventricular arrhythmias. Input was near uniform on the medical necessity of catheter ablation to treat ventricular tachycardia (VT) storm (incessant VT). Opinions were mixed whether catheter ablation should be the first-line treatment for VT storm but were near uniform on its use in patients with VT storm that fails to respond to pharmacologic treatment.

### Practice Guidelines and Position Statements

#### Supraventricular Arrhythmias

#### American College of Cardiology et al

The 2015 American College of Cardiology, American Heart Association, and Heart Rhythm Society guidelines on the management of adults with supraventricular arrhythmias included the following recommendations for catheter ablation (see Table 1).<sup>9</sup>

**Table 1. Guidelines on Management of Adults With Supraventricular Arrhythmias**

Recommendation	COR	LOE
PSVT (AVNRT):		
• Recurrent, symptomatic AVNRT	I	B
• Infrequent AVNRT in patients who desire complete control of arrhythmia	I	B
• Infrequent, well-tolerated AVNRT	I	B
SVT of unknown mechanism:		
• With pre-excitation present in sinus rhythm	I	B
• Without pre-excitation present in sinus rhythm	I	B
Focal atrial tachycardia	I	B

Recommendation	COR	LOE
Symptomatic AVNRT; ablation of slow pathway	I	B-NR
Orthodromic AVRT, ablation of accessory pathway	I	B-NR
Asymptomatic pre-excitation:		
• EP study identifies high risk of arrhythmic events	IIa	B-NR
• Pre-excitation precludes employment	IIa	B-NR
Atrial flutter:		
• Symptomatic or refractory to rate control pharmacologic treatment	I	B-R
• Recurrent, symptomatic and has failed at least 1 rhythm control pharmacologic treatment	I	C-LD
• Occurs as the result of flecainide, propafenone, or amiodarone	IIa	C-LD
• Recurrent, symptomatic non-CTI dependent flutter as primary therapy, before therapeutic trials	IIa	C-LD
• Asymptomatic with recurrent atrial flutter	IIb	C-LD
Junctional tachycardia:		
• Drug therapy options are contraindicated or ineffective	IIb	C-LD
• Recurrent, symptomatic SVT in ACHD	IIa	B-NR
• Undergoing planned surgical repair of structural heart disease or ischemic heart disease	IIa	B-NR
Pregnant, with highly symptomatic, recurrent, drug-refractory SVT	IIb	C-LD

ACHD: adult congenital heart disease; AVRT: atrioventricular reciprocating tachycardia; AVNRT: atrioventricular nodal reentrant tachycardia; COR: class of recommendation; CTI: cavotricuspid isthmus; EP: electrophysiology; LOE: level of evidence; PSVT: paroxysmal supraventricular tachycardia; SVT: supraventricular tachycardia.

## Ventricular Arrhythmias

### *European Society for Cardiology*

In 2015, the European Society for Cardiology released guidelines on the management of patients with ventricular arrhythmias and the prevention of sudden cardiac death.<sup>41</sup> The guidelines were based on a comprehensive review of published evidence, and the level of evidence and strength of recommendations were weighed and graded (see Table 2).

**Table 2. Guidelines on Management of Ventricular Arrhythmias and Sudden Cardiac Death**

Recommendation	COR	LOE
Urgent catheter ablation is recommended in patients with scar-related heart disease presenting with incessant VT or electrical storm	I	B
Catheter ablation is recommended in patients with ischemic heart disease and recurrent ICD shocks due to sustained VT	I	B
Catheter ablation should be considered after a first episode of sustained VT in patients with ischemic heart disease and an ICD	IIa	B
Radiofrequency catheter ablation at a specialized ablation center followed by the implantation of an ICD should be considered in patients with recurrent VT, VF or electrical storms despite complete revascularization and optimal medical treatment	IIa	C
Catheter ablation should be considered in patients with LV dysfunction associated with PVCs	IIa	B
Urgent catheter ablation in specialized or experienced centers is recommended in patients presenting with incessant VT or electrical storm resulting in ICD shocks	I	B
Amiodarone or catheter ablation is recommended in patients with recurrent ICD shocks due to sustained VT	I	B
Amiodarone or catheter ablation should be considered after a first episode of sustained VT in patients with an ICD	IIa	B
Catheter ablation as a first-line therapy is recommended in patients presenting with bundle branch re-entrant tachycardia	I	C
Catheter ablation is recommended in patients with DCM and bundle branch re-entry ventricular tachycardia refractory to medical therapy	I	B
Catheter ablation may be considered in patients with DCM and VA not caused by bundle branch re-entry refractory to medical therapy	IIb	C
Catheter ablation, performed in experienced centers, should be considered in patients with frequent symptomatic PVC or VT unresponsive to medical therapy to improve symptoms and prevent ICD shocks, respectively	IIa	B
Catheter ablation may be considered in patients with a history of electrical storms or repeated appropriate ICD shocks	IIb	C

Recommendation	COR	LOE
Medical therapy or catheter is recommended in children with frequent PVCs or VT thought to be causative of ventricular dysfunction	I	C
Catheter ablation should be considered when medical therapy is either not effective or undesired in symptomatic children with idiopathic RVOT VF/PVCs or verapamil-sensitive left fascicular VT	IIa	B
Catheter ablation by experience operators should be considered after failure of medical therapy or as an alternative to chronic medical therapy in symptomatic children with idiopathic LVOT, aortic cusps or epicardial VT/PVCs	IIa	B
Catheter ablation is not recommended in children < 5 years of age except when previous medical therapy fails or when VT is not hemodynamically tolerated	III	B
Catheter ablation is recommended as additional therapy or an alternative to ICD in patients with CHD who have recurrent monomorphic VT or appropriate ICD therapies that are not manageable by device reprogramming or drug therapy	I	C
Catheter ablation should be considered as an alternative to drug therapy for symptomatic sustained monomorphic VT in patients with CHD and an ICD	IIa	B
Surgical ablation by electrophysiological mapping may be considered in patients with CHD undergoing cardiac surgery, with clinical sustained VT and with inducible sustained monomorphic VT with an identified critical isthmus	IIb	C
Catheter ablation or prophylactic anti-arrhythmic therapy is not recommended for asymptomatic infrequent PVC in patients with CHD and stable ventricular function	III	C
Catheter ablation of RVOT VT/PVC is recommended in symptomatic patients and/or in patients with a failure of anti-arrhythmic drug therapy (e.g. beta-blocker) or in patients with a decline in LV function due to RVOT-PVC burden	I	B
Catheter ablation of LVOT/aortic cusp/epicardial VT/PVC by experienced operators after failure of one or more sodium channel blockers (class IC agents) or in patients not wanting long-term anti-arrhythmic drug therapy should be considered in symptomatic patients	IIa	B
Catheter ablation by experienced operators is recommended as a first-line treatment in symptomatic patients with idiopathic left VTs	I	B

CHD: congenital heart disease; COR: class of recommendation; DCM: dilated cardiomyopathy; ICD: implantable cardioverter defibrillator; LOE: level of evidence; LV: left ventricular; LVOT: left ventricular outflow tract; PVC: premature ventricular complex; RVOT: right ventricular outflow tract; VA: ventricular arrhythmia; VF: ventricular fibrillation; VT: ventricular tachycardia.

### *American College of Cardiology et al*

The American College of Cardiology, American Heart Association, and Heart Rhythm Society (2017) released joint guidelines on the management of patients with ventricular arrhythmias and the prevention of sudden cardiac death.<sup>42</sup> Table 3 summarizes the guidelines on cardiac ablation.

**Table 3. Guidelines on Management of Ventricular Arrhythmias and Sudden Cardiac Death**

Recommendation	COR	LOE
In patients with ischemic heart disease and ICD shocks for sustained monomorphic VT or symptomatic sustained monomorphic VT that is recurrent, or hemodynamically tolerated, catheter ablation as first-line therapy may be considered to reduce recurrent VA	IIb	C-LD
In patients with NICM and recurrent sustained monomorphic VT who fail or are intolerant of antiarrhythmic medications, catheter ablation can be useful for reducing recurrent VT and ICD shocks	IIa	B-NR
In patients with symptomatic VA arising from the papillary muscles for whom antiarrhythmic medications are ineffective, not tolerated, or not the patient's preference, catheter ablation is useful	I	B-NR
For patients who require arrhythmia suppression for symptoms or declining ventricular function suspected to be due to frequent PVCs (generally >15% of beats and predominately of 1 morphology) and for whom antiarrhythmic medications are ineffective, not tolerated, or not the patient's preference, catheter ablation is useful	I	B-NR
In patients with adult CHD and complex or sustained VA in the presence of important residual hemodynamic lesions, treatment of hemodynamic abnormalities with catheter or surgical intervention as feasible is indicated prior to consideration of ablation or an ICD	I	B-NR
In patients with adult CHD with recurrent sustained monomorphic VT or recurrent ICD shocks for VT, catheter ablation can be effective	IIa	B-NR

Recommendation	COR	LOE
In patients with bundle-branch reentrant VT, catheter ablation is useful for reducing the risk of recurrent VT and ICD shocks	I	C-LD
In patients with structural heart disease who have failed endocardial catheter ablation, epicardial catheter ablation can be useful for reducing the risk of recurrent monomorphic VT	Ila	B-NR

CHD: congenital heart disease; COR: class of recommendation; ICD: implantable cardioverter-defibrillator; NICM: nonischemic cardiomyopathy; PVC: premature ventricular complex; VA: ventricular arrhythmia; VT: ventricular tachycardia.

### *European Heart Rhythm Association et al*

The European Heart Rhythm Association (2017) released a consensus document on the management of supraventricular arrhythmias. This statement was endorsed by 3 other cardiology associations.<sup>43</sup> Table 4 summarizes the recommendations on cardiac ablation.

**Table 4. Guidelines on the Management of SVT**

Guideline	Recommendation
<b>Chronic therapy of SVTs in ACHD patients</b>	
<i>If recurrent symptomatic SVT...</i>	
Catheter ablation may be considered.	May be used or recommended
<i>If there is a planned surgical repair and symptomatic SVT...</i>	
In patients with SVT planned for surgical repair of Ebstein's anomaly, preoperative catheter ablation or intraoperative surgical ablation of accessory pathways, flutter or AT may be considered.	May be used or recommended
<b>Recommendations for treatment of SVT during pregnancy</b>	
Catheter ablation may be considered in highly symptomatic, drug refractory SVT after the first trimester	May be used or recommended

ACHD: adult congenital heart disease; AT: atrial tachycardia; SVT: supraventricular tachycardia.

The consensus document also provided recommendations on the use of catheter ablation (see Table 5).

**Table 5. Guidelines on Catheter Ablation**

Guideline	Recommendation
<b>Sinus tachycardia</b>	
Catheter ablation should not be routinely considered in patients with inappropriate sinus tachycardia.	Should NOT be used or recommended
Catheter ablation may be used in patients with symptomatic sinus nodal reentrant tachycardia.	May be used or recommended
<b>Therapy of focal atrial tachycardia</b>	
Catheter ablation is recommended, especially for incessant atrial tachycardia	May be used or recommended
<b>Therapy of AVNRT</b>	
Catheter ablation for slow pathway modification is recommended in symptomatic patients or in patients with an implantable cardioverter-defibrillator.	Recommended/indicated
<b>Therapy of focal junctional tachycardia</b>	
Catheter ablation may be considered but at a risk of atrioventricular block.	May be used or recommended
<b>Therapy of AVRT due to manifest or concealed accessory pathways</b>	
Catheter ablation of the accessory pathway is recommended in patients with symptomatic AVRT and/or pre-excited atrial fibrillation.	Recommended/indicated
Catheter ablation of concealed accessory pathways may be considered in symptomatic patients with frequent episodes of AVRT	May be used or recommended
<b>Management of asymptomatic pre-excitation</b>	
Catheter ablation of accessory pathways may be considered in asymptomatic patients with accessory pathways with antegrade refractory period < 240 ms, inducible	May be used or recommended

Guideline	Recommendation
atrioventricular reentrant tachycardia triggering pre-excited atrial fibrillation, and multiple accessory pathways.	
AVNRT: atrioventricular nodal reentrant tachycardia; AVRT: atrioventricular reentrant tachycardia.	

### Ventricular and Supraventricular Arrhythmias in Pediatric Patients

#### *European Heart Rhythm Association et al*

The European Heart Rhythm Association and the Association for European Paediatric and Congenital Cardiology (2013) released a joint consensus statement on pharmacologic and nonpharmacologic therapies for arrhythmia in the pediatric population.<sup>44</sup> These guidelines addressed the use of catheter ablation for supraventricular and ventricular arrhythmias in both structurally normal hearts and in repaired and unrepaired congenital heart disease. In general, given the higher risk of radiofrequency ablations in the pediatric age group compared with adults and the limited data on the long-term effects of radiofrequency lesions in the immature myocardium, the authors recommended that radiofrequency catheter ablation in infants and young children be considered only when all antiarrhythmic therapies have failed. Table 6 provides consensus statement recommendations for catheter ablation for pediatric patients with structurally normal hearts.

**Table 6. Guidelines on Pharmacologic and Nonpharmacologic Therapies for Pediatric Arrhythmia**

Recommendation	COR	LOE
<b>WPW syndrome</b>		
WPW syndrome and episode of aborted SCD	I	C
WPW syndrome and syncope combined with pre-excited RR interval during AF <250 ms or antegrade APERP during PES <250 ms	I	C
WPW syndrome and recurrent and/or symptomatic SVT and age >5 years	I	C
WPW syndrome and recurrent and/or symptomatic SVT and age <5 years	IIb	C
WPW syndrome and palpitations with inducible sustained SVT during EP test, age >5 years	I	C
Asymptomatic pre-excitation, age >5 years, no recognized tachycardia, risks and benefits of procedure and arrhythmia clearly explained	IIb	C
Asymptomatic pre-excitation, age <5 years	III	C
<b>Supraventricular tachycardia</b>		
Incessant or recurrent SVT associated with ventricular dysfunction	I	C
Single or infrequent SVT (no pre-excitation), age >5 years	IIb	C
SVT, age >5 years, chronic AA therapy has been effective in control of the arrhythmia	IIa	C
SVT, age <5 years (including infants), when AA medications, including classes I and III are not effective or associated with intolerable side effects	IIa	C
SVT controlled with conventional AA medications, age >years	III	C
<b>Ventricular arrhythmias</b>		
Recurrent monomorphic VT with hemodynamic compromise and amenable to catheter ablation	I	C

AA: antiarrhythmic; AF: atrial fibrillation; APERP: accessory pathway effective refractory period; COR: class of recommendation; EP: electrophysiologic; LOE: level of evidence; PES: programmed electrical stimulation; SCD: sudden cardiac death; SVT: supraventricular tachycardia; VT: ventricular tachycardia; WPW: Wolf-Parkinson-White.

The European Heart Rhythm Association and 2 other European cardiology associations (2018) released a position paper on congenital heart disease among youth and young adults. This paper was endorsed by 4 other domestic and European cardiology societies.<sup>45</sup> Table 7 summarizes the recommendations on cardiac ablation.

**Table 7. Guidelines of Therapy for Young Adults with CHD**

Guideline	Recommendation
<b>SVT catheter ablation</b>	
The use of catheter ablation is recommended for individuals with symptomatic sustained recurrent SVT over long-term medical therapy, especially in simple CHD scenarios	Recommended/indicated



Guideline	Recommendation
In simple CHD substrates, ablation of symptomatic MRAT is generally recommended as an alternative to antiarrhythmic drugs and/or electrical cardioversions.	Recommended/indicated
The use of 3D mapping systems and irrigated tip catheters is recommended for MRAT ablation in patients with CHD	Recommended/indicated
Atrial fibrillation ablation is recommended in certain simple CHD patients, at experienced centers	May be used or recommended
The use of atrioventricular blockade and permanent pacing (third-line therapy) is recommended when all other medical and ablative therapies have failed	Recommended/indicated
The use of catheter ablation for atrial tachycardia is not recommended when it can be controlled medically in the early post-surgical period (<3 months)	Should NOT be used or recommended
Catheter ablation is not recommended for asymptomatic non-sustained runs of atrial tachycardia.	Should NOT be used or recommended

CHD: congenital heart disease; MRAT: macroreentrant atrial tachycardia; SVT: supraventricular tachycardia.

### *Pediatric and Congenital Electrophysiology Society et al*

The Pediatric and Congenital Electrophysiology Society and Heart Rhythm Society (2012) published an expert consensus statement on the management of the asymptomatic young patient (age range, 8-21 years) with a Wolf-Parkinson-White electrocardiogram pattern, which was endorsed by 4 North American cardiology societies.<sup>46</sup> Statements relevant to the use of catheter ablation are included in Table 8.

**Table 8. Guidelines on Use of Catheter Ablation to Manage Asymptomatic Young Patients with Wolff-Parkinson-White Patterns**

Recommendation	COE	LOE
3. "Young patients with a SPERRI $\leq$ 250 ms in atrial fibrillation are at increased risk for SCD. It is reasonable to consider catheter ablation in this group, taking into account the procedural risk factors based on the anatomical location of the pathway."	IIA	B/C
4. "Young patients with a SPERRI >250 ms in atrial fibrillation are at lower risk for SCD, and it is reasonable to defer ablation. Ablation may be considered in these patients at the time of diagnostic study if the location of the pathway and/or patient characteristics do not suggest that ablation may incur an increased risk of adverse events, such as AV block or coronary artery injury."	IIA IIB	C C
5. "Young patients deemed to be at low risk might subsequently develop cardiovascular symptoms such as syncope or palpitations. These patients should then be considered symptomatic and may be eligible for catheter ablation procedures regardless of the prior assessment."		
6. "Asymptomatic patients with a WPW ECG pattern and structural heart disease are at risk for both atrial tachycardia and AV reciprocating tachycardia, which may result in unfavorable hemodynamics. Ablation may be considered regardless of the anterograde characteristics of the accessory pathway."	IIB	C
7. "Asymptomatic patients with a WPW ECG pattern and ventricular dysfunction secondary to dyssynchronous contractions may be considered for ablation, regardless of anterograde characteristics of the bypass tract."	IIA	C

AV: atrioventricular; COE: class of evidence; ECG: electrocardiogram; LOE: level of evidence; SCD: sudden cardiac death; SPERRI: shortest excited R-R interval; WPW: Wolff-Parkinson-White.

### U.S. Preventive Services Task Force Recommendations

Not applicable.

### Medicare National Coverage

There is no national coverage determination. In the absence of a national coverage determination, coverage decisions are left to the discretion of local Medicare carriers.

### Ongoing and Unpublished Clinical Trials

Some currently unpublished trials that might influence this review are listed in Table 9.

Table 9. Summary of Key Trials

NCT No.	Trial Name	Planned Enrollment	Completion Date
<b>Ongoing</b>			
NCT02130765 <sup>a</sup>	Substrate Targeted Ablation Using the FlexAbility™ Ablation Catheter System for the Reduction of Ventricular Tachycardia (STAR-VT) - G130132	1453	Jun 2017 (ongoing)
NCT02772354	Radiofrequency Ablation of Symptomatic Frequent Ventricular Premature Complexes as a First-line Therapy in Pediatric Population without Structural Heart Disease	124	Apr 2018 (ongoing)
NCT02303639	Medical ANtiarrhythmic Treatment or Radiofrequency Ablation in Ischemic Ventricular Tachyarrhythmias. A Prospective, Randomized Multicentre Study	120	Jun 2018
NCT02501005 <sup>a</sup>	Preventive aBlation of vEntricular tachycardia in Patients with myocardial Infarction (BERLIN VT)	208	Dec 2020

NCT: national clinical trial.

<sup>a</sup> Denotes industry-sponsored or cosponsored trial.

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## Documentation for Clinical Review

### Please provide the following documentation:

- History and physical and/or cardiology consultation notes including:
  - Symptoms, duration and type of arrhythmia
  - Pertinent ECGs or rhythm tracings showing the problem to be treated
  - Previous treatments and response including any antiarrhythmic drug trials (medication, dose, duration, response)
  - Location of arrhythmogenic focus to be treated (if applicable)
  - Type of ablation to be performed (e.g., radiofrequency or cryoablation)
- Physician progress notes pertaining to the request
- Pertinent laboratory or imaging studies

### Post Service (in addition to the above, please include the following):

- Cardiology procedure report(s)

## Coding

*This Policy relates only to the services or supplies described herein. Benefits may vary according to product design; therefore, contract language should be reviewed before applying the terms of the Policy.*

*The following codes are included below for informational purposes. Inclusion or exclusion of a code(s) does not constitute or imply member coverage or provider reimbursement policy. Policy Statements are intended to provide member coverage information and may include the use of some codes for clarity. The Policy Guidelines section may also provide additional information for how to interpret the Policy Statements and to provide coding guidance in some cases.*

Type	Code	Description
CPT®	0745T	Cardiac focal ablation utilizing radiation therapy for arrhythmia; noninvasive arrhythmia localization and mapping of arrhythmia site (nidus), derived from anatomical image data (e.g., CT, MRI, or myocardial perfusion scan) and electrical data (e.g., 12-lead ECG data), and identification of areas of avoidance <i>(Code effective 1/1/2023)</i>
	0746T	Cardiac focal ablation utilizing radiation therapy for arrhythmia; conversion of arrhythmia localization and mapping of arrhythmia site (nidus) into a multidimensional radiation treatment plan <i>(Code effective 1/1/2023)</i>
	0747T	Cardiac focal ablation utilizing radiation therapy for arrhythmia; delivery of radiation therapy, arrhythmia <i>(Code effective 1/1/2023)</i>
	93650	Intracardiac catheter ablation of atrioventricular node function, atrioventricular conduction for creation of complete heart block, with or without temporary pacemaker placement
	93653	Comprehensive electrophysiologic evaluation with insertion and repositioning of multiple electrode catheters, induction or attempted induction of an arrhythmia with right atrial pacing and recording and catheter ablation of arrhythmogenic focus, including intracardiac electrophysiologic 3-dimensional mapping, right ventricular pacing and recording, left atrial pacing and recording from coronary sinus or left atrium, and His bundle recording, when performed; with treatment of supraventricular tachycardia by ablation of fast or slow atrioventricular pathway, accessory atrioventricular connection, cavo-tricuspid isthmus or other single atrial focus or source of atrial re-entry
	93654	Comprehensive electrophysiologic evaluation with insertion and repositioning of multiple electrode catheters, induction or attempted induction of an arrhythmia with right atrial pacing and recording and catheter ablation of arrhythmogenic focus, including intracardiac electrophysiologic 3-dimensional mapping, right ventricular pacing and recording, left atrial pacing and recording from coronary sinus or left atrium, and His bundle recording, when performed; with treatment of ventricular tachycardia or focus of ventricular ectopy including 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)
HCPCS	None	

### Policy History

This section provides a chronological history of the activities, updates and changes that have occurred with this Medical Policy.

Effective Date	Action
07/31/2015	BCBSA Medical Policy adoption
11/01/2016	Policy revision without position change
12/01/2017	Policy revision without position change
09/01/2018	Policy number change from 2.02.01 Policy revision without position change

Effective Date	Action
08/01/2019	Policy revision without position change
07/01/2020	Annual review. No change to policy statement.
07/01/2021	Annual review. No change to policy statement.
02/01/2022	Coding update.
07/01/2022	Annual review. No change to policy statement.
03/01/2023	Coding update.
06/01/2023	Annual review. No change to policy statement.

## Definitions of Decision Determinations

**Medically Necessary:** Services that are Medically Necessary include only those which have been established as safe and effective, are furnished under generally accepted professional standards to treat illness, injury or medical condition, and which, as determined by Blue Shield, are: (a) consistent with Blue Shield medical policy; (b) consistent with the symptoms or diagnosis; (c) not furnished primarily for the convenience of the patient, the attending Physician or other provider; (d) furnished at the most appropriate level which can be provided safely and effectively to the patient; and (e) not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of the Member's illness, injury, or disease.

**Investigational/Experimental:** A treatment, procedure, or drug is investigational when it has not been recognized as safe and effective for use in treating the particular condition in accordance with generally accepted professional medical standards. This includes services where approval by the federal or state governmental is required prior to use, but has not yet been granted.

**Split Evaluation:** Blue Shield of California/Blue Shield of California Life & Health Insurance Company (Blue Shield) policy review can result in a split evaluation, where a treatment, procedure, or drug will be considered to be investigational for certain indications or conditions, but will be deemed safe and effective for other indications or conditions, and therefore potentially medically necessary in those instances.

## Prior Authorization Requirements (as applicable to your plan)

Within five days before the actual date of service, the provider must confirm with Blue Shield that the member's health plan coverage is still in effect. Blue Shield reserves the right to revoke an authorization prior to services being rendered based on cancellation of the member's eligibility. Final determination of benefits will be made after review of the claim for limitations or exclusions.

Questions regarding the applicability of this policy should be directed to the Prior Authorization Department at (800) 541-6652, or the Transplant Case Management Department at (800) 637-2066 ext. 3507708 or visit the provider portal at [www.blueshieldca.com/provider](http://www.blueshieldca.com/provider).

We are interested in receiving feedback relative to developing, adopting, and reviewing criteria for medical policy. Any licensed practitioner who is contracted with Blue Shield of California or Blue Shield of California Promise Health Plan is welcome to provide comments, suggestions, or concerns. Our internal policy committees will receive and take your comments into consideration.

For utilization and medical policy feedback, please send comments to: [MedPolicy@blueshieldca.com](mailto:MedPolicy@blueshieldca.com)

*Disclaimer: This medical policy is a guide in evaluating the medical necessity of a particular service or treatment. Blue Shield of California may consider published peer-reviewed scientific literature, national guidelines, and local standards of practice in developing its medical policy. Federal and state law, as well as contract language,*

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*including definitions and specific contract provisions/exclusions, take precedence over medical policy and must be considered first in determining covered services. Member contracts may differ in their benefits. Blue Shield reserves the right to review and update policies as appropriate.*



**Appendix A**

POLICY STATEMENT (No changes)	
BEFORE	AFTER
<p><b>Catheter Ablation for Cardiac Arrhythmias BSC2.12</b></p> <p><b>Policy Statement:</b></p> <ol style="list-style-type: none"> <li>I. Catheter ablation may be considered <b>medically necessary</b> for the treatment of supraventricular tachyarrhythmias, for <b>any</b> of the following:                             <ol style="list-style-type: none"> <li>A. Treatment of atrial flutter</li> <li>B. Treatment of focal atrial tachycardia</li> <li>C. Treatment of paroxysmal supraventricular tachycardia due to accessory pathways</li> <li>D. Treatment of paroxysmal supraventricular tachycardia due to atrioventricular nodal reentry tachycardia</li> </ol> </li>   <li>II. Catheter ablation using radiofrequency energy may be considered <b>medically necessary</b> for the treatment of chronic, recurrent, ventricular tachycardia that is refractory to implantable cardioverter defibrillator treatment and antiarrhythmic medications, and for which an identifiable arrhythmogenic focus can be identified.</li>   <li>III. Catheter ablation for ventricular tachycardia storm (see Policy Guidelines section) may be considered <b>medically necessary</b> when pharmacologic treatment has been unsuccessful in controlling the arrhythmia.</li>   <li>IV. Catheter ablation for all other ventricular arrhythmias is considered <b>investigational</b>.</li> </ol>	<p><b>Catheter Ablation for Cardiac Arrhythmias BSC2.12</b></p> <p><b>Policy Statement:</b></p> <ol style="list-style-type: none"> <li>I. Catheter ablation may be considered <b>medically necessary</b> for the treatment of supraventricular tachyarrhythmias, for <b>any</b> of the following:                             <ol style="list-style-type: none"> <li>A. Treatment of atrial flutter</li> <li>B. Treatment of focal atrial tachycardia</li> <li>C. Treatment of paroxysmal supraventricular tachycardia due to accessory pathways</li> <li>D. Treatment of paroxysmal supraventricular tachycardia due to atrioventricular nodal reentry tachycardia</li> </ol> </li>   <li>II. Catheter ablation using radiofrequency energy may be considered <b>medically necessary</b> for the treatment of chronic, recurrent, ventricular tachycardia that is refractory to implantable cardioverter defibrillator treatment and antiarrhythmic medications, and for which an identifiable arrhythmogenic focus can be identified.</li>   <li>III. Catheter ablation for ventricular tachycardia storm (see Policy Guidelines section) may be considered <b>medically necessary</b> when pharmacologic treatment has been unsuccessful in controlling the arrhythmia.</li>   <li>IV. Catheter ablation for all other ventricular arrhythmias is considered <b>investigational</b>.</li> </ol>