

(20201)

Medical Benefit		Effective Date: 07/01/12	Next Review Date: 05/18
Preauthorization	No	Review Dates: 05/12, 05/13, 05/14, 05/15, 05/16, 05/17	

Preauthorization is not required.

The following protocol contains medical necessity criteria that apply for this service. The criteria are also applicable to services provided in the local Medicare Advantage operating area for those members, unless separate Medicare Advantage criteria are indicated. If the criteria are not met, reimbursement will be denied and the patient cannot be billed. Please note that payment for covered services is subject to eligibility and the limitations noted in the patient's contract at the time the services are rendered.

Populations	Interventions	Comparators	Outcomes
Individuals: <ul style="list-style-type: none"> With supraventricular arrhythmias 	Interventions of interest are: <ul style="list-style-type: none"> Catheter ablation 	Comparators of interest are: <ul style="list-style-type: none"> Medication therapy 	Relevant outcomes include: <ul style="list-style-type: none"> Overall survival Symptoms Change in disease status Morbid events Medication use Treatment-related morbidity
Individuals: <ul style="list-style-type: none"> With drug- and implantable cardioverter defibrillator-refractory ventricular tachycardia due to structural heart disease 	Interventions of interest are: <ul style="list-style-type: none"> Catheter ablation 	Comparators of interest are: <ul style="list-style-type: none"> Medication therapy 	Relevant outcomes include: <ul style="list-style-type: none"> Overall survival Symptoms Change in disease status Morbid events Medication use Treatment-related morbidity
Individuals: <ul style="list-style-type: none"> With idiopathic ventricular tachycardia refractory to drug therapy and implantable cardioverter defibrillator placement 	Interventions of interest are: <ul style="list-style-type: none"> Catheter ablation 	Comparators of interest are: <ul style="list-style-type: none"> Medication therapy 	Relevant outcomes include: <ul style="list-style-type: none"> Overall survival Symptoms Change in disease status Morbid events Medication use Treatment-related morbidity
Individuals: <ul style="list-style-type: none"> With ventricular tachycardia storm who have failed pharmacologic treatment 	Interventions of interest are: <ul style="list-style-type: none"> Catheter ablation 	Comparators of interest are: <ul style="list-style-type: none"> Medication therapy 	Relevant outcomes include: <ul style="list-style-type: none"> Overall survival Symptoms Change in disease status Morbid events Medication use Treatment-related morbidity

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 different energy sources can be used with catheter ablation, such as radiofrequency and/or cryotherapy.

Summary of Evidence

For individuals who have supraventricular arrhythmias who receive catheter ablation, the evidence includes numerous case series and uncontrolled trials and one randomized controlled trial (RCT). 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 consisting of 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 qualitatively that the technology results in a meaningful improvement in the net health outcome.

For individuals with drug- and implantable cardioverter defibrillator-refractory ventricular tachycardia due to structural heart disease who receive catheter ablation, the evidence consists of systematic reviews of RCTs. Relevant outcomes are overall survival, symptoms, change in disease status, morbid events, medication use, and treatment-related morbidity. Across nine individual RCTs that evaluated catheter ablation versus usual care with medical management and one RCT that directly compared escalation of antiarrhythmic medications to catheter ablation in patients with ventricular tachycardia (VT) 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% and associated with approximately a 50% reduction in inappropriate ICD interventions compared to 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 one- to two-year follow-ups and 40% to 50% remain VT free after six years of follow-up. The trial directly comparing catheter ablation to escalation of medication found a 28% lower rate of a composite of death, VT storm, and appropriate ICD shock among patients undergoing catheter ablation versus those receiving an escalation in antiarrhythmic drug therapy. The evidence is sufficient to determine qualitatively 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 and low rates of adverse events 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 has been 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. However, in these situations, morbidity and mortality are expected to be extremely high in patients who have failed pharmacologic therapy; therefore, the available evidence is considered

sufficient to draw conclusions about outcomes. The evidence is sufficient to determine qualitatively that the technology results in a meaningful improvement in the net health outcome.

Policy

Catheter ablation may be considered **medically necessary** for the treatment of supraventricular tachyarrhythmias, as follows:

- Treatment of paroxysmal supraventricular tachycardia due to AV nodal re-entry tachycardia
- Treatment of paroxysmal supraventricular tachycardia due to accessory pathways
- Treatment of atrial flutter
- Treatment of focal atrial tachycardia.

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.

Catheter ablation for ventricular tachycardia storm (see Policy Guidelines), may be considered **medically necessary** when pharmacologic treatment has been unsuccessful in controlling the arrhythmia.

Catheter ablation for all other ventricular arrhythmias is considered **investigational**.

Policy Guidelines

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

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

VT storm, also known as incessant VT, is defined as at least three episodes of sustained VT in a 24-hour period. VT storm is considered a life-threatening situation that requires prompt attention and treatment.

This protocol does not address catheter ablation for atrial fibrillation; please refer to the Catheter Ablation as Treatment for Atrial Fibrillation Protocol if atrial fibrillation is a consideration.

Background

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 such as 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 VT or reentrant VTs 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 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 for initial imaging. 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 and whether there are underlying structural abnormalities of the heart. Various complications have been documented; they include:

- **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 (TIA). The estimated incidence of stroke or TIA 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, such as the use of electroanatomic mapping and remote navigation systems, are available.

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.

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

Related Protocols

Catheter Ablation as Treatment for Atrial Fibrillation

Implantable Cardioverter Defibrillator

Services that are the subject of a clinical trial do not meet our Technology Assessment Protocol criteria and are considered investigational. *For explanation of experimental and investigational, please refer to the Technology Assessment Protocol.*

It is expected that only appropriate and medically necessary services will be rendered. We reserve the right to conduct prepayment and postpayment reviews to assess the medical appropriateness of the above-referenced procedures. **Some of this protocol may not pertain to the patients you provide care to, as it may relate to products that are not available in your geographic area.**

References

We are not responsible for the continuing viability of web site addresses that may be listed in any references below.

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