Transcatheter Ablation of Arrhythmogenic Foci in the Pulmonary Veins as Treatment for Atrial Fibrillation

Type: Medical Necessity and Investigational / Experimental

Policy Specific Section: Surgery

Original Policy Date: August 1, 2006

Effective Date: December 19, 2013

Definitions of Decision Determinations

Medically Necessary: A treatment, procedure or drug is medically necessary only when it has been established as safe and effective for the particular symptoms or diagnosis, is not investigational or experimental, is not being provided primarily for the convenience of the patient or the provider, and is provided at the most appropriate level to treat the condition.

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.

Description

Atrial fibrillation (AF) is the most common sustained cardiac arrhythmia. In AF, abnormal impulses spread across the atrium, interfering with normal heart rhythm. The contractions of the atrium are rapid, chaotic and ineffective and may cause dizziness, fatigue and the development of
blood clots that may lead to stroke. Various catheter ablation techniques have been investigated to treat AF. There has been recent recognition that the most common focal trigger of AF appears to be located within the myocytes extending into the pulmonary veins. This finding creates a potential target for transcatheter ablation in the atrium of the heart and in the pulmonary veins to interrupt the pathways along which abnormal electrical impulses travel. Unlike conservative treatments for AF such as medications and cardioversion, ablation is intended to be curative. Three basic ablation strategies which target the arrhythmogenic foci in the pulmonary veins have emerged:

- Focal ablation inside the pulmonary veins
- Segmental ablation of the ostia of the pulmonary veins
- Circumferential ablation of the atrial wall outside the ostia of the pulmonary veins

**Policy**

Transcatheter radiofrequency ablation of arrhythmogenic foci in the pulmonary veins may be considered **medically necessary** for the treatment of medication resistant atrial fibrillation for either of the following indications:

- Symptomatic paroxysmal or persistent atrial fibrillation
- Class II or III congestive heart failure and symptomatic atrial fibrillation

Repeat transcatheter radiofrequency ablation of arrhythmogenic foci in the pulmonary veins may be considered **medically necessary** for recurrence of atrial fibrillation and/or development of atrial flutter following the initial procedure.

Transcatheter cryoablation/cryoballoon ablation of arrhythmogenic foci in the pulmonary veins may be considered **medically necessary** for the treatment of drug-refractory paroxysmal atrial fibrillation.

Transcatheter radiofrequency ablation or cryoablation/cryoballoon ablation of the pulmonary veins is considered **investigational** as a treatment for all other indications, except for specific cases of atrial fibrillation as noted in the policy statements above.

**Policy Guideline**

Note: For members who undergo an electrophysiology (EP) study on the same day as an ablation, an EP study is considered medically necessary if no prior EP study has been performed within the previous three months. Transcatheter ablation in pulmonary veins for atrial fibrillation (AF) can be performed by a single electrophysiologist but a second electrophysiologist can be allowed as an assistant surgeon. In the latter, one electrophysiologist manipulates the catheters and the other guides the precise location for the ablation utilizing electrogram analysis and pacing. The procedure may require temporary pacemaker placement if indicated. If ablation is of the His-bundle, a permanent pacemaker will always be placed because the ablation causes complete heart block.
Repeat Procedures:
As many as 30% of patients will require a follow-up (repeat) procedure due to recurrence of atrial fibrillation or to developing atrial flutter. In most of the published studies, success rates were based on having as many as 3 separate procedures, although these repeat procedures may be more limited than the initial procedure.

Contraindications to Antiarrhythmic Drugs:
Contraindications to antiarrhythmic drugs may include, but are not limited to:

- Advanced conduction disease (particularly second or third degree heart block in the absence of a pacemaker)
- Advanced heart failure or markedly depressed cardiac function with the exception of amiodorone and dofetilide
- Drug hypersensitivity
- Gastrointestinal bleed
- Prolonged Q-T interval
- Syncope or weakness when taking antiarrhythmic drugs

Coding:
Beginning in 1/1/2013, there is a new CPT code specific to pulmonary vein ablation:

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

This new combination code is not to be used with any of the following CPT codes: 93279-93284, 93286-93289, 93462, 93600, 93602, 93603, 93610, 93612, 93618, 93619, 93620, 93621, 93653, or 93654.

There is also a CPT add-on code for additional atrial fibrillation therapy after the pulmonary vein isolation procedure:

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

Regulatory Status
In February 2009, the NAVISTAR® THERMOCOOL® Irrigated Deflectable Diagnostic/Ablation Catheter and EZ Steer ThermoCool NAV Catheter (Biosense Webster Inc.) were approved by the U.S. Food and Drug Administration (FDA) through the pre-market approval (PMA) process for “catheter-based cardiac electrophysiologic mapping (stimulating and recording), and when used with the Stockert 70 generator, for the treatment of a) Type I atrial flutter in patients age 18 or older; b) recurrent drug/device refractory sustained monomorphic ventricular tachycardia (VT) due to prior myocardial infarction (MI) in adults; c)
drug refractory recurrent symptomatic paroxysmal atrial fibrillation, when used with compatible three-dimensional electroanatomic mapping systems.” (For radiofrequency ablation)

In December 2010, Medtronic’s Arctic Front® Cardiac CryoAblation Catheter and CryoConsole were approved by the FDA for the “treatment of drug refractory recurrent symptomatic paroxysmal atrial fibrillation.” In addition, Medtronic’s Freezor® MAX Cardiac CryoAblation Catheter was approved as an adjunctive device to be used in conjunction with the Arctic Front system for “gap cryoablation to complete electrical isolation of the pulmonary veins, cryoaoblution of focal trigger sites, and creation of ablation line between the inferior vena cava and the tricuspid valve.” (For cryoaoblution)

In addition, the FDA has also granted PMA approval to numerous catheter ablation systems for other ablation therapy for arrhythmias such as supraventricular tachycardia, atrial flutter, and ventricular tachycardia.

<table>
<thead>
<tr>
<th>Documentation Required for Clinical Review</th>
</tr>
</thead>
<tbody>
<tr>
<td>• History and physical and/or cardiology consultation reports including:</td>
</tr>
<tr>
<td>◦ Symptoms and duration of atrial fibrillation</td>
</tr>
<tr>
<td>◦ Previous treatment plan and response</td>
</tr>
<tr>
<td>◦ Antiarrhythmic drug trials (medication, dose, duration, response)</td>
</tr>
<tr>
<td>◦ NYHA classification of congestive heart failure (if applicable)</td>
</tr>
<tr>
<td>◦ Type of ablation to be performed (e.g., radiofrequency or cryoaoblution)</td>
</tr>
<tr>
<td>• Physician progress notes pertaining to the request</td>
</tr>
<tr>
<td>Post Service</td>
</tr>
<tr>
<td>• Cardiology procedure report(s)</td>
</tr>
</tbody>
</table>

The materials provided to you are guidelines used by this plan to authorize, modify, or deny care for persons with similar illness or conditions. Specific care and treatment may vary depending on individual need and the benefits covered under your contract. These Policies are subject to change as new information becomes available.