



CIGNA MEDICAL COVERAGE POLICY

The following Coverage Policy applies to all plans administered by CIGNA Companies including plans administered by Great-West Healthcare, which is now a part of CIGNA.

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

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Coverage Policy

CIGNA covers transcatheter ablation of the pulmonary veins (pulmonary vein isolation) as medically necessary as an alternative to long-term antiarrhythmic drug therapy for the treatment of atrial fibrillation when BOTH of the following criteria are met:

- individual has symptomatic recurrent paroxysmal or persistent atrial fibrillation
- little or no left atrial enlargement is present

General Background

Atrial fibrillation (AF) is a frequently diagnosed cardiac arrhythmia characterized by uncoordinated atrial activation with deterioration of atrial mechanical function. AF is seen on electrocardiogram (ECG) as the replacement of consistent P waves with rapid oscillations or fibrillatory waves that vary in size, shape, and timing, associated with an irregular, frequently rapid ventricular response when atrioventricular (AV) conduction is intact. The initial episode of AF is categorized as "first detected". AF is considered recurrent when a patient has had two or more episodes. Once terminated, recurrent AF is designated as paroxysmal, and is designated as persistent when it is sustained. AF is still designated as persistent even when terminated by pharmacological therapy or electrical cardioversion. Persistent AF may be the first presentation or a result of recurrent episodes

of paroxysmal AF. Persistent AF includes longstanding cases in which cardioversion has been either not indicated or not attempted. AF is associated with an increased risk of stroke because of the potential for thrombus formation in the relatively stagnant atrial blood. When low or high ventricular response rates accompany AF, dangerous ventricular arrhythmias may occur, resulting in syncope, myocardial infarction or death (Fuster, et al., 2006)

The management of patients with AF includes three objectives: rate control, prevention of thromboembolus, and correction of the rhythm disturbance. These treatment objectives are not mutually exclusive. With a rate-control treatment strategy, the ventricular rate is controlled with no commitment to restore or maintain sinus rhythm, while the rhythm-control strategy is intended to restore and/or maintain sinus rhythm. Rhythm control also requires attention to rate control. If the initial treatment strategy is unsuccessful, the alternate strategy is usually adopted. Regardless of whether rate control or rhythm control is the primary strategy, attention must be paid to antithrombotic therapy for the prevention of thromboembolism. Transcatheter ablation of the AV node and accessory pathways, if present, followed by pacemaker insertion may be used for rate control when pharmacological treatment is ineffective or not tolerated. Although AV node ablation may provide symptom relief, this is not a curative procedure. Although rate control may be achieved, lifelong pacemaker dependency results, and long-term anticoagulation is required, since the atria continue to fibrillate (Fuster, et al., 2006).

Transcatheter ablation is used to destroy myocardial tissue by delivering energy over electrodes on a catheter placed next to an area of the endocardium determined to be integral to the onset and/or maintenance of the arrhythmia. Early radiofrequency ablation techniques, modeled after the surgical Maze procedure, created linear scars in the atrial epicardium. Although this approach may be useful in patients who have had recurrent fibrillation after an apparently successful isolation procedure, it has largely been replaced by transcatheter ablation of arrhythmogenic foci in the pulmonary veins. A high percentage of patients with paroxysmal AF have excitatory foci in the superior aspect of the left atrium, in close proximity to the pulmonary veins. Specifically, the small area of cardiac muscle extending across the ostium of each pulmonary vein is notable for the frequent presence of excitatory foci. The prospect of elimination of AF by elimination of these foci caused renewed interest in catheter-based ablation.

Transcatheter ablation of arrhythmogenic foci in the pulmonary veins is also referred to as pulmonary vein isolation (PVI), because the ablation is intended to interrupt conduction of the abnormal excitatory foci from the pulmonary veins to other areas of the atria. Several catheters with specialized tips are used to perform radiofrequency ablation. Access to the left atrium is typically obtained using a special transseptal-sheath-dilator combination inserted into the femoral vein and advanced over a guidewire into the right atrium. Using this system, the atrial septum is punctured, allowing access by ablation catheters to the pulmonary veins (Libby: Braunwald's Heart Disease, 2007; Jahangiri, et al., 2006).

Left atrial enlargement is associated with AF and is a strong predictor of recurrence. AF can be more easily induced and maintained in an enlarged atrium, and conversion to sinus rhythm is less likely to be maintained in the presence of left atrial enlargement (Weigner et al., 1999; Lee et al., 2005).

Ablation Energy Sources: Several energy sources have been employed in cardiac ablation procedures. Ideally, the energy source and device should achieve transmural, cause no damage to adjacent structures, provide fast application and have malleable, non-bulky probes. Initial ablation procedures almost exclusively used radiofrequency energy. Radiofrequency is most commonly employed for catheter ablation procedures. The primary method of tissue destruction by radiofrequency current is thermal injury. Other sources of energy currently used for ablation procedures include microwave and cryotherapy (Blue Cross Blue Shield TEC, 2006; Jahangiri, et al., 2006).

Heating is also the mechanism of microwave ablation. Microwaves cause oscillation of water molecules in the tissue, converting electromagnetic energy into heat. Microwave ablation is reported to allow deeper, more even penetration through cardiac muscle when compared to radiofrequency. A single linear line of tissue coagulation approximately 5 by 5 mm is created. The problem of excessive surface heating at the contact point sometimes seen with radiofrequency is overcome with microwave treatment, and since the energy coming from the probe is unidirectional, surrounding tissues are protected. Although there are several studies on the use of microwave ablation in the surgical treatment of AF, the epicardial approach is less often applied. Cryotherapy causes tissue ablation when intracellular ice crystals disrupt cell membranes, leaving collagen structure intact. Cryotherapy lesions heal by fibrosis, forming a dense homogenous lesion. Cryotherapy can be provided both endocardially

and epicardially and does not produce char. Although the original cryoprobes were rigid and difficult to use, newer probes have a flexible cooling segment that can be shaped for use in different anatomic structures (Fuster, et al., 2006; Mokadam, et al., 2004; Jahangiri, et al., 2006).

Literature Review

Wilber et al. (2010) conducted a multicenter randomized controlled trial to determine the efficacy of catheter ablation compared to antiarrhythmic drug therapy (ADT) for the treatment of symptomatic paroxysmal atrial fibrillation (AF). Patients who had not responded to at least one antiarrhythmic drug and who experienced at least three AF episodes within six months before randomization were assigned 2:1 to ablation (n=106) or to a previously unused antiarrhythmic drug (n=61). At nine months, 66% of patients in the ablation group remained free of protocol-defined treatment failure, compared to 16% of patients in the ADT group. Major treatment-related adverse events occurred within 30 days in 5 of 57 patients (8.8%) in the ADT group compared to 5 of 103 patients (4.9%) in the ablation group. At three months, mean quality of life scores improved significantly in patients treated by catheter ablation compared to those treated with ADT, and improvement was maintained during the nine month evaluation period.

Oral et al. (2006) conducted a randomized controlled trial to determine the efficacy of circumferential radiofrequency pulmonary vein ablation (PVA) in maintaining sinus rhythm in the absence of antiarrhythmic drug therapy (ADT) in patients with chronic AF (n=146). Patients were randomly assigned to receive amiodarone and undergo two cardioversions during the first three months alone (n=69), or in combination with circumferential PVA (n=77). At one year, 74% of patients in the ablation group were free of recurrent AF or flutter without ADT. Of 69 patients in the control group, 53 (77%) crossed over to undergo circumferential PVA by one year. Only three (4%) of the patients in the control group were in sinus rhythm without ADT or ablation for comparison with the treatment group. The authors concluded that sinus rhythm can be maintained long-term in the majority of patients with chronic AF by means of circumferential PVA independent of the effects of ADT, cardioversion or both.

Stabile et al. (2006) conducted a randomized controlled trial (n=137) to investigate the adjunctive role of ablation therapy to ADT in preventing AF relapse in patients with paroxysmal or persistent AF in whom ADT had failed. Patients were randomized to ablation and ADT (n=68, ablation group) or ADT alone (n=69, control group). The ablation group received cavo-tricuspid and left inferior pulmonary vein mitral isthmus ablation plus circumferential pulmonary vein ablation using radiofrequency. The primary end point was the absence of recurrence of atrial arrhythmia lasting more than 30 seconds in the one-year follow-up period after a one-month blanking period. A blanking period is a time interval during which success criteria are not evaluated. Left atrial ablation procedures used to treat AF may not decrease the incidence of AF until four to six weeks following ablation. At twelve months, 63 of 69 (91.3%) patients in the control group had at least one AF recurrence, compared to 30 of 68 (44.1%) patients in the ablation group. The authors noted that most studies have used surrogate end points such as time to first symptomatic atrial arrhythmia recurrence, whereas this study chose the time to first recurrence, whether symptomatic or not, to define success. This may explain the lower success rate (56%) compared to previously published studies. The authors concluded that ablation therapy combined with ADT is superior to ADT alone in preventing atrial arrhythmia recurrences in patients with paroxysmal or persistent AF in whom antiarrhythmic drug therapy has failed.

Pappone et al. (2006) conducted a randomized controlled trial to evaluate circumferential pulmonary vein ablation compared to antiarrhythmic drug therapy (ADT) for paroxysmal AF (n=198). Patients with paroxysmal AF of six \pm five years' duration were randomized to radiofrequency ablation (n=99) or to the maximum tolerable dose of another antiarrhythmic drug. A repeat ablation was performed in 9% of patients in the ablation group for recurrent AF (6%) or atrial tachycardia (3%). The primary end point was freedom from documented recurrent atrial tachyarrhythmias (AT) during a 12-month follow-up. The end point was reached with the first episode of AT, and cases with a second antiarrhythmic drug or repeat ablation procedure were considered failures. At one year, 93% of patients in the ablation group and 35% of patients in the ADT group were AT-free. One transient ischemic attack and one pericardial effusion occurred in the ablation group. Side effects of antiarrhythmics were observed in 23 patients in the ADT group. The authors concluded that, among selected patients with a long history of paroxysmal AF, a single circumferential pulmonary vein ablation is more effective than ADT with three antiarrhythmic drugs widely used as single agents or in combination.

Systematic Reviews

Calkins et al. (2009) conducted two separate systematic reviews and meta-analyses, one on radiofrequency ablation (RFA) and one on antiarrhythmic drug therapy (ADT), to evaluate the clinical efficacy and safety of both therapies in the treatment of AF. All study designs were accepted for the RFA systematic review, while the ADT therapy review was limited to prospective studies on the following drugs: amiodarone, dofetilide, sotalol, flecainide, and propafenone. Sixty-three RFA studies (n=8789) and 34 ADT studies (n=6589) were included in the reviews. Patients in the RFA studies tended to be younger than those in the ADT trials, with a mean age of 55 vs. 62 years; had a longer duration of AF (6.0 vs. 3.1 years); and had failed more previous drug trials (2.6 vs. 1.7). The single-procedure success rate of RFA was 57% and the multiple-procedure success rate was 71% for patients not on ADT therapy. The multiple-procedure success rate for patients on ADT or with unknown ADT usage was 77%. The success rate for ADT therapy was 52%. A major complication occurred in 4.9% of catheter ablation patients. Adverse events were more common in ADT studies than in RFA studies, at 30% vs. 5%, respectively, but were less severe.

A 2009 Agency for Healthcare Research and Quality (AHRQ) comparative effectiveness review evaluated the evidence for the short-and long-term clinical effect and safety of radiofrequency catheter ablation for the management of AF. The review concluded that there is a moderate level of evidence to show that patients treated with radiofrequency ablation as a second-line therapy (i.e., patients who did not respond to medical therapy) had a higher chance of maintaining sinus rhythm than those treated with medical therapy alone. There was insufficient evidence to compare freedom from AF recurrence in patients who had radiofrequency ablation as first line therapy vs. medically treated patients. The review also states that there is a low level of evidence to show that nonparoxysmal AF is predictive of a higher rate of AF recurrence, and there is a high level of evidence demonstrating that sex, presence of structural heart disease, and duration of AF are not associated with recurrence.

An ECRI Evidence Report evaluated PVI for atrial fibrillation, based on a systematic review of 17 studies; ten controlled trials comparing interventions, and seven large case series of PVI reporting complications. The report concluded that, for the restoration of a normal heart rhythm, the evidence is sufficient to conclude that PVI is more likely to achieve this result than medications. In addition, PVI generally results in fewer hospital stays than medications alone. The authors stated that these outcomes are likely related, since hospitalization may occur because of a potentially dangerous recurrence of AF. The report also states that the possible benefits of PVI must be balanced against the possible harms. Serious rare events, including PVS, and cardiac tamponade, may occur, although the rates of these events are generally low (e.g., 1%). Antiarrhythmic medications also have adverse effects, and it is not clear whether PVI or medications have the less harmful profile, or whether the potential benefits of PVI outweigh any potential risks (ECRI, 2008).

A systematic review conducted by Noheria et al. (2008) to assess whether circumferential pulmonary vein ablation is superior to ADT in the treatment of atrial fibrillation. The meta-analysis included the trials by Pappone, Stabile, and Wazni, discussed above, and a trial conducted by Krittayaphong (2003). Of 214 patients in the pulmonary veins isolation group, 162 (75.7%) had atrial tachyarrhythmia recurrence-free survival at 12 months, compared to 41 of 218 patients (18.8%) in the ADT group. In addition, fewer adverse events were reported in the ablation group compared to the ADT group. Because of the limited number of studies evaluated, the authors cautioned that these conclusions must be taken as confirmation of the need for further trials and not as a guide for clinical practice.

Blue Cross/Blue Shield Technology Evaluation Center (TEC)

A Blue Cross/Blue Shield TEC Assessment (2008) evaluated six randomized controlled trials to determine whether radiofrequency catheter ablation improves health outcomes when used as a treatment for patients with AF. All trials reported substantial differences in favor of the ablation group on relevant outcomes, particularly in AF recurrence. The authors stated that the consistency of this finding establishes catheter ablation as more effective than medications in maintaining sinus rhythm across a wide spectrum of patients with AF, and across different variations of catheter ablation. The recurrence rate varied widely, indicating that there may be differences in absolute efficacy for different populations of patients. It cannot be concluded with confidence, however, that the lack of reported recurrence represents the elimination of AF, since AF is often intermittent and of brief duration.

The assessment concluded that radiofrequency catheter ablation of the pulmonary veins as a treatment for AF meets the TEC criteria for:

- patients with symptomatic paroxysmal or persistent atrial fibrillation who have failed antiarrhythmic medications, as an alternative to continued medical management; and
- patients with class II or III congestive heart failure and symptomatic atrial fibrillation in whom heart rate is poorly controlled by standard medications, as an alternative to AV nodal ablation and pacemaker insertion.

For other patients with atrial fibrillation, including first-line treatment for paroxysmal AF, radiofrequency catheter ablation of the pulmonary veins does not meet the TEC criteria.

National Institute for Health and Clinical Excellence (NICE) (United Kingdom)

NICE Interventional Procedures Guidance issued in 2006 states that current evidence on the safety and efficacy of percutaneous radiofrequency ablation for atrial fibrillation appears adequate to support the use of this procedure in appropriately selected patients, provided that normal arrangements are in place for audit and clinical governance. The guidance document further states that the procedure is a treatment option for symptomatic patients with AF refractory to antiarrhythmic drug therapy, or where medical therapy is contraindicated because of comorbidity or intolerance.

Professional Societies/Organizations

The American College of Cardiology (ACC)/American Heart Association (AHA)/European Society of Cardiology (ESC) Guidelines for the Management of Patients with AF provided updated recommendations for catheter ablation in 2006 (Fuster, et al.). The guideline states that the initial and subsequent management of symptomatic AF differs among patients. For patients with symptomatic AF lasting for many weeks, initial therapy may be anticoagulation and rate control, with a long-term goal of restoration of sinus rhythm. If rate control offers inadequate relief of symptoms, restoration of sinus rhythm will become a clear long-term goal. Early cardioversion may be necessary if AF results in hypotension or worsening heart failure. In older patients, however, improvement of symptoms by rate control may direct treatment away from attempts to restore sinus rhythm.

Guideline recommendations are classified as follows:

- Class I: Conditions for which there is evidence for and/or general agreement that the procedure or treatment is beneficial, useful and effective
- Class II: Conditions for which there is conflicting evidence and/or a divergence of opinion about the usefulness/efficacy of the procedure or treatment
 - Class IIa: Weight of evidence/opinion is in favor of usefulness/efficacy
 - Class IIb: Usefulness/efficacy is less well-established by evidence/opinion
- Class III: Conditions for which there is evidence for and/or general agreement that the procedure or treatment is not useful or effective and in some cases may be harmful

The ACC/AHA/ESC guideline states that catheter ablation is a reasonable alternative to pharmacological therapy to prevent recurrent AF in symptomatic patients with little or no LA enlargement. The guideline classifies this procedure as a Class IIa recommendation.

The guideline states that the long-term efficacy of catheter ablation to prevent recurrent AF requires further study. Although available data demonstrate one year or more free from recurrent AF in carefully selected patients, it is important to be aware that AF may recur without symptoms and be unrecognized by the patient and physician. It is uncertain whether apparent cures represent true elimination of AF or a transition to an asymptomatic type of paroxysmal AF, a situation with important implications for determining the duration of anticoagulation therapy in patients at risk for stroke. The guideline also cites the limitation of a lack of information regarding late success of ablation in patients with heart failure and other structural heart disease who may be more likely to experience AF recurrence.

Complications of PV isolation noted in the ACC/AHA/ESC guideline included pulmonary vein stenosis, thromboembolism, atrioesophageal fistula and left atrial flutter, in addition to potential complications inherent in any cardiac catheterization procedure. The potential benefits and short- and long-term risks must be considered when determining which patients will benefit from ablation.

The Heart Rhythm Society (HRS)/European Heart Rhythm Association (EHRA)/European Cardiac Arrhythmia Society (ECAS) Consensus Statement on Catheter and Surgical Ablation of Atrial Fibrillation: Recommendations for Personnel, Policy, Procedures and Follow-up (Calkins, et al., 2007) supports the recommendations of the ACC/AHA/ESC 2006 guidelines detailed above. The report states that the task force, in particular, agrees that catheter ablation of AF in general should not be considered as first-line therapy. The following areas of consensus on ablative techniques were identified by the task force:

- Ablation strategies which target the pulmonary veins and/or pulmonary vein antrum are the cornerstone for most AF ablation procedures.
- If the pulmonary veins are targeted, complete electrical isolation should be the goal.
- Careful identification of the pulmonary vein ostia is mandatory to avoid ablation within the pulmonary veins.
- If a focal trigger is identified outside a pulmonary vein at the time of an AF ablation procedure, it should be targeted if possible.
- If additional linear lesions are applied, line completeness should be demonstrated by mapping or pacing maneuvers.
- Ablation of the cavotricuspid isthmus is recommended only in patients with a history of typical atrial flutter or inducible cavotricuspid isthmus-dependent atrial flutter
- If patients with longstanding persistent AF are approached, ostial pulmonary isolation alone may not be sufficient.

Summary

Transcatheter ablation of arrhythmogenic foci in the pulmonary veins, also referred to as pulmonary vein isolation (PVI), emerged as a treatment option when advances in electrophysiology revealed that a high percentage of patients with paroxysmal atrial fibrillation (AF) have excitatory foci in the superior aspect of the left atrium, in close proximity to the pulmonary veins. A number of studies have demonstrated that this treatment may be a reasonable option for patients with recurrent symptomatic paroxysmal or persistent AF when antiarrhythmic drug therapy (ADT) has failed to restore sinus rhythm or is contraindicated or not tolerated. This procedure may also be a reasonable option when recommended as an alternative to long-term ADT. Additional research is needed to determine optimal catheter placement, clear definition of treatment success, recurrence rates compared to pharmacological approaches for rhythm control, or, when unsuccessful, techniques of rate control such as AV node ablation and pacing.

Coding/Billing Information

Note: This list of codes may not be all-inclusive.

Covered when medically necessary when used to report transcatheter ablation of the pulmonary veins for the treatment of atrial fibrillation, including both transeptal puncture and ablation of the arrhythmogenic foci:

CPT®*	Description
93799	Unlisted cardiovascular service or procedure

ICD-9-CM Diagnosis Codes	Description
427.31	Atrial fibrillation

*Current Procedural Terminology (CPT®) © 2010 American Medical Association: Chicago, IL.

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Policy History

Pre-Merger Organizations	Last Review Date	Policy Number	Title
CIGNA HealthCare	12/15/2007	0469	Transcatheter Ablation of Arrhythmogenic Foci in the Pulmonary Veins for the Treatment of Atrial Fibrillation

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