



Cigna Medical Coverage Policy

Subject Electrophysiological 3-Dimensional Mapping

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Table of Contents

Coverage Policy	1
General Background	1
Coding/Billing Information	6
References	7
Policy History	12

Hyperlink to Related Coverage Policies

- [Maze Procedure](#)
- [Robotic Assisted Surgery](#)
- [Transcatheter Ablation of Arrhythmogenic Foci in the Pulmonary Veins for the Treatment of Atrial Fibrillation](#)

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Coverage Policy

Cigna covers the use of an intracardiac electrophysiological 3-dimensional mapping system as medically necessary when used to guide radiofrequency ablation in the treatment of supraventricular arrhythmias.

Cigna does not cover the use of an intracardiac electrophysiological 3-dimensional mapping system when utilized in the diagnosis, treatment, or management of ventricular arrhythmias because it is considered experimental, investigational or unproven.

General Background

The underlying cause of an arrhythmia provides the basis for selecting treatment. The least invasive treatment that controls the arrhythmia is the treatment of choice. The treatment options can include lifestyle changes, medications, devices, ablation procedures and surgery, including the implantation of pacemakers and defibrillators.

Cardiac ablation is typically used to treat rapid heartbeats that begin in the upper chambers, or atria, of the heart which are known as supraventricular tachycardias (SVTs). Types of SVTs are: atrial fibrillation (AF), atrial flutter, atrioventricular (AV) nodal reentrant tachycardia, AV reentrant tachycardia, and atrial tachycardia. Less frequently, ablation can treat heart rhythm disorders that begin in the heart's lower chambers, known as the ventricles. The most common, ventricular tachycardia, may also be the most dangerous type of arrhythmia

because it can cause sudden cardiac death. For many types of arrhythmias, catheter ablation is successful, therefore eliminating the need for open-heart surgeries or long-term drug therapies.

The conventional two-dimensional cardiac mapping procedure used to guide radiofrequency catheter ablation for the treatment of cardiac arrhythmias uses a roving mapping catheter, a computerized mapping system, and fluoroscopy to determine the location of the mapping catheter. In the conventional cardiac mapping procedure, both the patient and the electrophysiologist are exposed to potentially significant doses of ionizing radiation during the course of the lengthy procedure. The two-dimensional images produced by the fluoroscopy may not provide precise catheter location and do not allow for visualization of the endocardial surfaces. To improve the accuracy of cardiac mapping and reduce exposure to potentially dangerous ionizing radiation, three-dimensional (3-dimensional) magnetic navigation mapping systems have been developed. This has also been referred to as electroanatomic mapping.

Three-dimensional magnetic navigation mapping systems (e.g., CARTO™ EP Navigation System; EnSite™ System) are used to guide radiofrequency catheter ablation for the treatment of cardiac arrhythmias. These non-fluoroscopic, catheter-based, electro-anatomic mapping systems locate the arrhythmia focus or foci which deliver radiofrequency (RF) energy via an intracardiac catheter which destroys the targeted myocardial tissue. Three-dimensional mapping systems consist of a magnetic field generator locator pad which is placed under the patient's table or patches on the patient's skin track the catheter, a sensor-mounted catheter and a reference catheter placed intracardially, a mapping system, and a graphic computer. The mapping systems use algorithms to translate data on the catheter's location into a 3D image. A 3-dimensional map is generated, and sensor-mounted catheters are manipulated without fluoroscopy. Three-dimensional magnetic navigation mapping systems are sometimes called multi-modality mapping or image integration systems because they can show pictures or data from other sources. For instance, patient CT or MRI scans taken a few days or weeks before the procedure may be loaded onto the three-dimensional magnetic navigation mapping systems and matched with the real time 3D image of the heart. It is now standard to integrate patient-specific preacquired 3-dimensional models of the left atrium and pulmonary veins (generated using either contrast-enhanced computed tomography or magnetic resonance imaging) with mapping systems to guide better the ablation procedure (Kistler, et al.; 2008; Reddy, 2008; Akhtar, 2004; Kumar, et al., 2002).

Some of the procedure-reported complications during mapping procedures include catheter manipulation complications: perforation of the atrial appendage, heart or left atrium; and acute pericardial tamponade. Lower-extremity burns have been reported related to the reference patch interface and leg lead electrodes (Manufacturer and User Facility Device Experience Database [MAUDE], 2010). Cerebrovascular accident 24 hours after ablation, cardiac tamponade, complete AV block, severe pulmonary edema, and femoral arterial AV fistula requiring surgical repair have been reported in some the clinical studies (Verma, et al., 2005; Nademanee, et al., 2004).

Textbook literature on cardiac mapping states electrophysiological mapping systems been validated and used to facilitate mapping in patients with a variety of arrhythmias in all cardiac chambers. However, due to the sequential nature of map acquisition, use of this system is not recommended for patients with short-lived, polymorphic, or hemodynamic unstable arrhythmias, except for scar mapping and catheter navigation. The presence of extensive structural heart disease and multiple VTs contributes to difficulties in mapping and ablation of VT (Markides, et al., 2004).

Robotic or remote catheter navigation has been proposed to improve navigation precision and to shorten cardiac ablation procedures. A robotic ablation starts the same way as a traditional catheter ablation. The doctor inserts a catheter into the groin and guides the catheter to the right side of the heart. After making a puncture in the septum, the wall that separates the right and left sides of the heart, the doctor goes to the control system for the robotic system, which is usually located in an adjacent room. An example of robotic catheter system is the Niobe magnetic navigation system (Stereotaxis, Inc, St. Louis, MO) that only works with the CARTO electroanatomic mapping system (Biosense Webster, Inc., Diamond Bar, CA) and Biosense Webster mapping and ablation catheters. Another robotic navigation system is the Sensei® X Robotic Catheter System (Hansel Medical, Mountain View, CA) that works with the EnSite™ System (St Jude Medical, St. Paul, MN). For information on the coverage of robotic cardiac surgery, please refer to the Cigna Reimbursement Policy, Robotic Assisted Surgery (Akca, et al., 2012; ECRI, 2010).

U.S. Food and Drug Administration (FDA)

The CARTO® EP Navigation System (Biosense Webster, Inc., Diamond Bar, CA) received 510(k) premarket approval in December 1999 by the U.S. Food and Drug Administration (FDA) as a Class II device for catheter-based cardiac mapping (FDA, 1999). The FDA indications for use state the intended use of the CARTO EP Navigation System is catheter-based cardiac mapping. The CARTO EP Navigation System and accessories have had numerous enhancements with the latest device, the CARTO 3 Version 1.05 EP Navigation System and accessories, receiving 510(k) premarket approval in 2009 (FDA, 2009; FDA, 2006; FDA, 2000).

The EnSite™ System (St Jude Medical, St. Paul, MN) received 510(k) premarket approval in 2003 as a Class II device for electrophysiology cardiac mapping (FDA, 2003).

Literature Review

Supraventricular Arrhythmias: Evidence in the published, peer-reviewed medical literature supports the use of an intracardiac electrophysiological 3-dimensional mapping system to guide radiofrequency ablation for the treatment of supraventricular arrhythmias. Historically, fluoroscopy-guided radiofrequency ablation success rates have varied according to the type of arrhythmia treated. The ablation of AV nodal reentry and the elimination of accessory pathways have been reported to be successful in nearly 100% of patients. In contrast, successful fluoroscopy-guided radiofrequency ablation rates for atrial tachycardia have ranged from 70–85%. Since 3-dimensional-guided ablation results may vary according to the arrhythmia being treated, studies with selected subgroups oriented on the exact arrhythmia mechanism are required to assess outcomes. Although the outcomes are not stellar, 3-dimensional mapping allows for reduction in fluoroscopy time in the technically difficult ablation of recurrent drug-resistant ventricular tachycardia with an arrhythmogenic focus originating in the right ventricle or outside the right ventricular outflow tract (Miller, et al., 2011; Suleiman, et al., 2007; Earley, et al., 2006; Kalarus, et al., 2006; Spoton, et al., 2004; Kopelman, et al., 2003; Willems, et al., 2000; Kottamp, et al., 2000; Marchlinski, et al., 1998).

Ventricular Arrhythmias: Evidence in the published, peer-reviewed medical literature regarding the use of an intracardiac electrophysiological 3-dimensional mapping system for the treatment of ventricular arrhythmias revealed studies that are insufficient to make definitive conclusions. Well-designed control trials that evaluate safety, efficacy and long-term outcomes of the use of intracardiac electrophysiological 3-dimensional mapping systems for the treatment of ventricular arrhythmias are needed.

In a case series study, Marai et al. (2012) assessed the feasibility, safety and efficacy of ablation of scar-related VT. Eleven male patients with drug-refractory ischemic VT were referred for scar mapping and ablation procedures using the CARTO navigation system. Eleven clinical VTs were induced in all patients. An nodocardial circuit, identified by activation, entrainment and/or pace mapping, was found in eight patients with stable VT. These patients were mapped and ablated during VT. Three patients had predominantly unstable VT and linear ablation lesions were performed during sinus rhythm. Acute success was defined as termination of VT and/or non-inducibility during programmed electrical stimulation, was found in 9 patients (82%). During followup of at least three months, a significant reduction in tachyarrhythmia burden was observed in all patients who had successful initial ablation, except for one who had recurrence of VT two days after the procedure and died two weeks later. This study was limited by the small sample size and lack of long term follow-up.

In case series study, Nair et al. (2011) evaluated the efficacy of RFA of ventricular tachycardia (VT) using noncontact electro-anatomic mapping in patients with arrhythmogenic right ventricular dysplasia/cardiomyopathy (ARVD/C). Fifteen consecutive patients with ARVD/C and symptomatic VTs were included in the study. Eight patients had syncopal VTs. Two patients had recurrent VT while on AICD; in three patients, RFA was done prior to AICD implantation, and ten patients refused AICD. After obtaining activation maps, first, the clinical VT was targeted, and then, other VTs were sought. Twenty-five inducible VTs were mapped, and 22 of them were successfully ablated. In 13 out of 15 patients, all the clinical and inducible VTs were ablated. In two patients, nonclinical inducible VTs could not be ablated. At 25±16 months (2–52 months), all patients remained asymptomatic. Antiarrhythmic medications were discontinued after six months. Two patients had recurrence of non-clinical VT on follow-up. There were no episodes of asymptomatic VT recorded in five patients with AICD. The reported limitations of this study are that only five patients had AICD implanted and, hence, true recurrence of asymptomatic VT could be assessed only in these patients. Another limitation is the relatively short duration of follow-up in many patients, and four patients had not yet completed six months of drug-free follow-up.

In a cohort study, Suleiman et al. (2007) reported the early and late outcome in patients with different arrhythmias treated with radiofrequency ablation combined with the CARTO mapping and navigation system.

The study comprised 125 patients with different cardiac arrhythmias. Forty patients (32%) had previous failed conventional ablation or mapping procedures and were referred by other centers. The arrhythmia included AF (n=13), atrial flutter (n=38), atrial tachycardia (n=25), VT (n=24), AVR (n=9), and SVT (n=16). A total of 125 patients underwent electrophysiological study and electroanatomic mapping of the heart chambers. Radiofrequency ablation was applied in 108 patients and was acutely successful in 94 patients (87%). In the remaining 17 patients, radiofrequency ablation was not indicated in 9 patients with AVR, and no significant arrhythmia could be induced in the others (1 patient with atrial flutter, 5 patients with atrial tachycardia and 2 patients with VT). Supraventricular arrhythmias were identified in 92 patients (73 %) and ventricular arrhythmias in 33 (27%). Acute and late success rates, defined as termination of the arrhythmia without anti-arrhythmic drugs, were 87% and 76% respectively. One patient developed a clinically significant complication. After a mean follow-up of 33 ± 22 months (range 3–86), 10 (10.6%) of the 94 patients in whom success was achieved had recurrence of the same arrhythmia.

Satomi et al. (2006) assessed the reliability of CARTO for characterizing the entire reentrant circuit and/or responsible substrate for reentry, and test the features of CARTO-guided catheter ablation during VT or sinus rhythm. An EPS and catheter ablation were performed in 17 AVR patients using CARTO. All patients had sustained monomorphic VT with a left bundle branch block pattern morphology and were diagnosed with AVR. One of three antiarrhythmic drugs, including amiodarone, was ineffective in all the patients. Endocardial mapping during sinus rhythm demonstrated electrogram abnormalities extended from the tricuspid annulus or the right ventricular outflow tract in 16 of 17 patients. In 13 hemodynamically stable VTs, the reentrant circuits and critical slow conduction sites for the catheter ablation were investigated during VTs. The entire macro-reentrant pathway was identified in 6/13 stable VTs. In the remaining seven VTs, a focal activation pattern was found in four and an unidentifiable pattern in three. Catheter ablation successfully abolished all the macro-reentrant and focal tachycardias; however, it was not effective in three unidentifiable VTs. In the 13 cases with unstable VT, the linear conduction block zone was produced between the sites with abnormal electrograms and the tricuspid annulus. Twenty-three of 26 VTs (88%) became noninducible after the catheter ablation. During follow-up (26 ± 15 months), 13/17 patients remained free from any VT episodes.

For ablation of VT in patients after myocardial infarction, a 3-dimensional mapping system is often used. Volkmer et al. (2006) reported on VT ablation using CARTO in 47 patients, with a subgroup analysis comparing VT mapping with the results of mapping that had to be performed during sinus rhythm or pacing (substrate mapping). A CARTO map was performed and VT ablation attempted using two strategies: patients in the VT-mapping group had incessant VT (n=4) or inducible stable VT (n=18) such that the circuit of the clinical VT could be reconstructed using CARTO. During VT, the critical area of slow conduction was identified using diastolic potentials and conventional concealed entrainment pacing. The substrate-mapping group had initially inducible VT. A complete VT map was not possible because of catheter-induced mechanical block (n=6) or because hemodynamics deteriorated during the ongoing VT (n=19). Therefore, pathological myocardium was identified by fragmented, late- and/or low-amplitude (<1.5 millivolts [mV]) bipolar potentials during sinus rhythm or pacing, and the ablation site was primarily determined by pace mapping inside or at the border of this pathological myocardium. Acute ablation success in all patients with regard to non-inducibility of the clinical VT or any slower VT was 79% after a single ablation procedure, but increased to 95% after a mean of 1.2 ablation procedures. However, chronic success was 75% when it was defined as freedom from any ventricular tachyarrhythmia (VT or VF) during a follow-up of 25 ± 13 months. In the subgroup analysis, patients in the VT-mapping group were not significantly different from patients in the substrate-mapping group with regard to age, ejection fraction, VT cycle length, number of radiofrequency applications, use of an irrigated tip catheter, and ablation results. This study was not a randomized clinical trial comparing VT mapping and substrate mapping. The authors noted that even if VT cannot be mapped with CARTO, the outcome was the same, which may lead to the assumption that a complete 3-dimensional VT map is not necessary in any patient undergoing VT ablation.

Verma et al. (2005) reported on the results and success of substrate-VT ablation in AVR. Due to hemodynamic instability, multiple morphologies, or noninducibility, VT ablation in patients with AVR may be limited. In this study, 22 patients underwent sinus rhythm CARTO mapping to define areas of scar and abnormal myocardium. Traditional mapping for VT was limited due to multiple/changing VT morphologies, nonsustained VT, or hemodynamic intolerance. Ablation was performed in abnormal regions targeting sites with good pace maps compared with the induced VT(s). Linear lesions were created in those areas to connect the scar/abnormal region to valve continuity or other scar or encircle the scar/abnormal region. Seven patients had VT, 18 had implanted cardioverter defibrillators, and 15 had implanted cardioverter defibrillator therapies. An average of 38 radiofrequency lesions were applied per patient. A serious complication occurred in one patient—

acute pericardial tamponade developed after ablation. Two patients had femoral hematomas that did not require treatment. Short-term success was achieved in 18 patients. VT recurred in 23%, 27%, and 47% of patients after one, two, and three years follow-up.

Boulos et al. (2005) studied the potential role of detailed electroanatomic mapping in differentiating patients who have right ventricular outflow tract (RVOT) tachycardia from those who have ARVD. Results of detailed electroanatomic mapping, with the CARTO system, of the right ventricle in a group of patients who had RVOT tachycardia was compared with those of the ARVD group and a control group of patients who had structurally normal ventricles and no ventricular arrhythmias. The RVOT tachycardia group consisted of 12 patients who had recurrent episodes of symptomatic tachycardia. Nine patients who had an electrophysiology study and radiofrequency ablation for different supraventricular tachyarrhythmias served as the control group. The third group consisted of nine patients who had ARVD. All patients in the study had some form of right ventricle structural abnormality. It was found that endocardial electrographic parameters do not differ between patients who have RVOT and control patients. RVOT tachycardia can be differentiated from ARVD by the absence of abnormal right ventricular electrographic findings. Differentiating the different pathologies that underlie right ventricle rhythm disorders, specifically between ARVD and RVOT tachycardia has important diagnostic, therapeutic, and prognostic implications.

Deneke et al. (2005) evaluated the efficacy of a substrate-based procedure to eliminate clinical VTs in patients with frequent medically-refractory ischemic VT. In 25 patients with a mean ejection fraction of 37% and with frequent symptomatic medically refractory (e.g., with recurrent ICD shocks), left ventricular anatomic mapping with CARTO was performed to modify the underlying myocardial substrate. Clinical VT, by linear catheter ablation, was eliminated in 92% of the patients. Linear ablation suppressed inducibility of all VTs in 70% of the patients. In 30% of the patients, only partial success could be established with arrhythmia recurrence early during follow-up in 50% of the patients.

Professional Societies/Organizations

The American College of Cardiology (ACC)/American Heart Association (AHA) Clinical Competence Statement on Invasive Electrophysiology Studies, Catheter Ablation, and Cardioversion: This evidence-based document was updated in 2006 by a joint task force of the ACC/AHA and the American College of Physicians, in collaboration with the Heart Rhythm Society. This statement addresses the use of emerging technology and new techniques in invasive cardiac EP procedures. Electroanatomic magnetic mapping capabilities are being applied to aid in the diagnosis and nonpharmacological treatment of arrhythmias. The authors state, "although not yet established as requisite or "core" equipment for the EP laboratory, these and other emerging technologies have had, and will continue to have, a major impact on the practice of cardiac arrhythmia management. It is also anticipated that additional new technologies will be developed at ever faster rates in the future" (Tracy, et al., 2006). There has been no update to this statement since 2006.

The ACC/AHA/European Society of Cardiology (ESC) Guidelines for Management of Patients with Ventricular Arrhythmias and the Prevention of Sudden Cardiac Death: In the ablation section of the guideline, the authors discuss 3-dimensional mapping in the subsection of structural heart disease. The guideline states that "VT is a common complication of structural heart disease and carries significant risk for mortality in coronary heart disease patients with low ejection fraction. In patients with extensive structural abnormalities, especially in patients with prior MI, multiple morphologies of VT are present. Therefore, ablation of a single VT morphology can provide palliation but does not eliminate the need for device or antiarrhythmic therapy. For those patients, VT can originate in, or involve extensive areas of the myocardium and standard radiofrequency delivery carries a low success rate. Given the inhomogeneous scarring present in ischemic VT, mapping techniques have evolved that take into account the complex nature of the circuits, including bystander regions of abnormal conduction. The newer 3-dimensional mapping systems permit anatomical reconstructions and correlation of EP characteristics with anatomy. These systems have led to an approach whereby circuits can be mapped during sinus rhythm and can facilitate ablation in the ischemic patient who often does not tolerate VT well. Use of these techniques may result in better long-term success rates" (Zipes, et al., 2006). There has been no update to this statement since 2006.

Summary

Evidence in the published, peer-reviewed medical literature supports the use of an intracardiac electrophysiological 3-dimensional mapping system (e.g., CARTO®, EnSite™ System) to guide radiofrequency ablation for the treatment of supraventricular arrhythmias.

Evidence in the published, peer-reviewed medical literature regarding the use of an intracardiac electrophysiological 3-dimensional mapping system for the treatment of ventricular arrhythmias revealed studies that are insufficient to make definitive conclusions. Well-designed control trials that evaluate safety, efficacy and long-term outcomes of the use of intracardiac electrophysiological 3-dimensional mapping systems for the treatment of ventricular arrhythmias are needed.

Coding/Billing Information

Note: 1) This list of codes may not be all-inclusive.

2) Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement.

Covered when medically necessary:

CPT[®]* Codes	Description
93613	Intracardiac electrophysiology 3- dimensional mapping (List separately in addition to code for primary procedure)
93620	Comprehensive electrophysiologic evaluation including insertion and repositioning of multiple electrode catheters with induction or attempted induction of arrhythmia; with right atrial pacing and recording, right ventricular pacing and recording, His bundle recording
93621	Comprehensive electrophysiologic evaluation including insertion and repositioning of multiple electrode catheters with induction or attempted induction of arrhythmia; with left atrial pacing and recording from coronary sinus or left atrium (List separately in addition to code for primary procedure)
93622	Comprehensive electrophysiologic evaluation including insertion and repositioning of multiple electrode catheters with induction or attempted induction of arrhythmia, with left ventricular pacing and recording (List separately in addition to code for primary procedure)
93624	Electrophysiologic follow-up study with pacing and recording to test effectiveness of therapy, including induction or attempted induction of arrhythmia
93651	Intracardiac cardiac ablation of arrhythmogenic focus; for treatment of supraventricular tachycardia by ablation of fast or slow atrioventricular pathways, accessory atrioventricular connections or other atrial foci, singly or in combination
93652	Intracardiac cardiac ablation of arrhythmogenic focus; for treatment of ventricular tachycardia

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

ICD-9-CM Diagnosis Codes	Description
427.0	Paroxysmal supraventricular tachycardia

Experimental/Investigational/Unproven/Not Covered when used to report intracardiac electrophysiological 3-dimensional mapping system when utilized in the diagnosis, treatment, or management of ventricular arrhythmias:

CPT* Codes	Description
93613	Intracardiac electrophysiology 3- dimensional mapping (List separately in addition to code for primary procedure)

HCCPS Codes	Description
C1732	Catheter, electrophysiology, diagnostic/ablation 3D or vector mapping

ICD-9-CM Diagnosis Codes	Description
427.1	Paroxysmal ventricular tachycardia
427.41	Ventricular fibrillation
427.42	Ventricular flutter
427.60	Premature beats, unspecified
427.69	Premature beats, other
427.9	Cardiac dysrhythmias, unspecified

***Current Procedural Terminology (CPT®) © 2011 American Medical Association: Chicago, IL.**

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Writing Committee to Develop Data Standards on Electrophysiology). ACC/AHA/HRS 2006 key data elements and definitions for electrophysiological studies and procedures: a report of the American College of Cardiology/American Heart Association Task Force on Clinical Data Standards (ACC/AHA/HRS Writing Committee to Develop Data Standards on Electrophysiology). *J Am Coll Cardiol*. 2006 Dec 5;48(11):2360-96.

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Policy History

<u>Pre-Merger Organizations</u>	<u>Last Review Date</u>	<u>Policy Number</u>	<u>Title</u>
Cigna HealthCare	6/15/2008	0074	CARTO [®] Electrophysiological Mapping

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