



# Medical Policy

<b>Subject:</b>	<b>Electrophysiology-Guided Noninvasive Stereotactic Cardiac Radioablation</b>	<b>Publish Date:</b>	<b>07/08/2020</b>
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## Description/Scope

**This document addresses the use of electrophysiology-guided noninvasive stereotactic cardiac radioablation as a treatment modality for cardiac arrhythmias, including drug and ablation refractory ventricular tachycardia (VT) and cardiomyopathy related to premature ventricular contractions (PVC).**

## Position Statement

### **Investigational and Not Medically Necessary:**

**The use of electrophysiology-guided noninvasive stereotactic cardiac radioablation is considered investigational and not medically necessary as a treatment modality for all indications, including drug and ablation refractory ventricular tachycardia and cardiomyopathy related to premature ventricular contractions.**

## Rationale

**Robinson and colleagues (2019) reported preliminary results from the electrophysiology-guided noninvasive cardiac radioablation for ventricular tachycardia (ENCORE-VT; NCT02919618) study, an ongoing prospective single-arm phase I/II study evaluating stereotactic body radiotherapy (SBRT), which involves noninvasive, image-guided, high-dose radiation therapy as a treatment modality for individuals who have drug- and ablation-refractory VT or cardiomyopathy related to PVCs. The study enrolled 19 participants; VT=17; PVC cardiomyopathy=2. No acute toxicity was observed during or immediately following SBRT, however, treatment-related serious adverse events were reported in 10.5% (2/19) of participants in the initial 90 days – one as treatment-related heart failure exacerbation, and another for pericarditis. Of the 18 participants who survived 6 months for post-procedure assessment, the primary efficacy endpoint, reduction in VT episodes or PVC burden was achieved in 17/18 (94%) participants. The median number of VT**

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episodes in the 6 months prior to treatment was reduced from 119 per participant (range, 4-292) to 3 (range, 0-31; p<0.001) in the 6-month postablation period (n=16 participants), and 24-hour PVC burden was reduced from 24% to 2% and 26% to 9% in the 2 relevant participants. "Reduction was observed for both implantable cardioverter defibrillator shocks and antitachycardia pacing. VT episodes or PVC burden was reduced in 17/18 evaluable participants (94%)." At 6 months, the overall survival was 89% and 72% at 12 months. There was a decrease in reported dual antiarrhythmic medications from 59% to 12% (p=0.008). At 6 months, quality of life reported by Short Form-36 improved in 5 of 9 domains.

While the technique appears to be a promising alternative to drug and ablation refractory arrhythmias with the exception of cardiac transplantation, further evaluation is required. Current data is limited to small case series, and a small non-randomized prospective study. There is insufficient evidence regarding the long-term safety and efficacy of noninvasive electrophysiology-guided cardiac radioablation as a treatment modality for drug- and ablation-refractory ventricular arrhythmias; further evaluation of the necessity or optimal patient selection with a multi-institutional trial is needed.

In 2020 Lloyd and colleagues reported results from a small, single-center, retrospective analysis of an investigational therapy under compassionate use under Institutional Review Board that reviewed stereotactic body radiation for refractory VT in advanced heart failure. The study considered participants for SBRT with at least two of the following characteristics: 1) failure of at least two antiarrhythmic drugs; 2) failed at least one RF ablation; and 3) "failed at least one adjunctive therapy such as mechanical support or sympathetic blockade defined as a recurrent VT defined after intervention". An SBRT treatment was performed in 10 participants (mean age 61 years); 40% (4/10) had ischemic heart failure and 60% (6/10) had non ischemic heart failure. Implantable cardioverter-defibrillator (ICD) data was available among 8 participants; a total reduction in seconds of detected VT was 69% (pretreatment 1065 seconds/month vs posttreatment 332 seconds/month). There was a 48% total reduction in antitachycardia pacing (ATP) sequences reported (17.3 pretreatment and 1.9 posttreatment). There was a 68% reported reduction in total ICD shocks after SBRT (2.9 shocks/month pretreatment and 0.9 shocks/month posttreatment). The authors concluded, "noninvasive treatment with SBRT was feasible and modestly effective at reducing VT burden in the critically ill. This suggests that SBRT treatment may be a useful palliation for electrical storm. Further randomized, prospective series are needed."

Varian Medical Systems (Palo Alto, CA) is the manufacturer of CyberHeart Cardiac radioablation using radiation oncology and cardiac electrophysiology. First in-human studies of radioablation in the treatment of

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cardiac arrhythmias are being conducted in ongoing trial (ENCORE-VT; NCT02919618). Estimated study completion date January 2024.

### Background/Overview

According to the American Heart Association (2016), ventricular arrhythmia often is related to interference in the electrical conduction in the heart associated to lack of coronary artery blood flow, cardiomyopathy, medication side effects, illicit drug use or sarcoidosis. Treatment options for VT include medical management, radiofrequency ablation (RFA), surgery, and in extreme cases immediate electrical defibrillation. In the United States, VT or ventricular fibrillation (VF) is responsible for most of the sudden cardiac deaths with nearly 300,000 cases reported per year.

Electrophysiology-guided noninvasive cardiac radioablation is a novel technique that delivers high doses of radiation to precise anatomic locations in the heart using stereotactic body radiotherapy (SBRT). Arrhythmogenic scar regions are targeted by combining noninvasive anatomic and electric cardiac imaging with a standard stereotactic body radiation therapy workflow followed by delivery of a single fraction of 25 gray (Gy) to the target. In preclinical studies, SBRT has demonstrated the ability to result in myocardial fibrosis and electrically inert tissue, similar to catheter ablation techniques. The technique has been proposed as a treatment alternative for individuals who have failed catheter ablation, or for those who choose to defer ablation given its associated risks.

### Definitions

Arrhythmia (or dysrhythmia): Problems that affect the electrical system of the heart muscle, producing abnormal heart rhythms and may be classified as either atrial or ventricular, depending on which part of the heart they originate from.

Guideline-directed medical therapy (GDMT): For context within this document, this terminology, which was formerly referred to as “Optimal medical therapy,” is defined as the use of at least 2 classes of medication to reduce symptoms, (for example, in the treatment of angina symptoms, drugs such as beta blockers, calcium channel blockers, nitrate preparations, ranolazine are used). In the event that an individual is unable to tolerate the medications, the maximum tolerated level of medical therapy will be considered to be maximal GDMT.

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**Non-sustained/Sustained Ventricular Tachycardia: Ventricular tachycardia is considered non-sustained (NSVT) when 3 or more consecutive ventricular beats occur at a rate of at least 120 beats/minute which lasts less than 30 seconds. If the rhythm lasts more than 30 seconds, it is known as a sustained ventricular tachycardia (even if it terminates on its own, [that is, without medical intervention] after 30 seconds).**

**Ventricular Tachycardia (Vtach or VT): This is a fast regular heart rate (usually of 100 or more beats per minute) that starts in the lower chambers (ventricles) and may result from serious heart disease that usually requires prompt treatment.**

### **Coding**

*The following codes for treatments and procedures applicable to this document are included below for informational purposes. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement policy. 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.*

**When services are Investigational and Not Medically Necessary:**

**For the following procedure and diagnosis codes; or when the code describes a procedure indicated in the Position Statement section as investigational and not medically necessary.**

#### **CPT**

**77299**

**Unlisted procedure, therapeutic radiology clinical treatment planning [when specified as planning for electrophysiology-guided noninvasive stereotactic cardiac radioablation]**

**77399**

**Unlisted procedure, medical radiation physics, dosimetry and treatment devices, and special services [when specified as electrophysiology-guided noninvasive stereotactic cardiac radioablation]**

**77373**

**Stereotactic body radiation therapy, treatment delivery, per fraction to 1 or more lesions, including image guidance, entire course not to exceed 5 fractions**

**77435**

**Stereotactic body radiation therapy, treatment management, per treatment course, to 1 or more lesions, including image guidance, entire course not to exceed 5 fractions**

#### **ICD-10 Diagnosis**

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<u>I42.1</u>	<u>Obstructive hypertrophic cardiomyopathy</u>
<u>I47.0-I47.9</u>	<u>Paroxysmal tachycardia</u>
<u>I49.01-I49.02</u>	<u>Ventricular fibrillation and flutter</u>
<u>I49.3</u>	<u>Ventricular premature depolarization</u>
<u>I49.40-I49.49</u>	<u>Other and unspecified premature depolarization</u>
<u>I49.9</u>	<u>Cardiac arrhythmia, unspecified</u>

**References**

**Peer Reviewed Publications:**

1. Cuculich PS, Schill MR, Kashani R, et al. Noninvasive cardiac radiation for ablation of ventricular tachycardia. N Engl J Med. 2017; 377(24):2325-2336.
2. Kim EJ, Davogusto G, Stevenson WG, John RM. Non-invasive cardiac radiation for ablation of ventricular tachycardia: A new therapeutic paradigm in electrophysiology. Arrhythm Electrophysiol Rev. 2018;7(1):8-10.
3. Lloyd MS, Wright J, Schneider F, et al. Clinical experience of stereotactic body radiation for refractory ventricular tachycardia in advanced heart failure patients. Heart Rhythm. 2020; 3:415-422.
4. Robinson CG, Samson PP, Moore KMS, et al. Phase I/II Trial of Electrophysiology-Guided Noninvasive Cardiac Radioablation for Ventricular Tachycardia. Circulation. 2019; 139(3):313-321.
5. Robinson C, Cuculich PS. Noninvasive cardiac radioablation for VT: lessons learned and future directions. Expert analysis. June 2019; available at: <https://www.acc.org/latest-in-cardiology/articles/2019/06/04/13/45/noninvasive-cardiac-radioablation-for-vt>. Accessed on March 4, 2020.

**Government Agency, Medical Society, and Other Authoritative Publications:**

1. Al-Khatib SM, Stevenson WG, Ackerman MJ, et al. 2017 AHA/ACC/HRS Guideline for management of patients with ventricular arrhythmias and the prevention of sudden cardiac death. J Amer Coll Cardiol. 2018; 72(14):e91-e220.
2. Washington University School of Medicine. Phase I/II study of EP-guided noninvasive cardiac radioablation for treatment of ventricular tachycardia (ENCORE-VT). NLM Identifier: NCT02919618. Last updated September 10, 2019. Available at: <https://clinicaltrials.gov/ct2/show/NCT02919618>. Accessed on March 4, 2020.

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Websites for Additional Information

1. **American Heart Association. About arrhythmia. September 30, 2016. Available at: [http://www.heart.org/HEARTORG/Conditions/Arrhythmia/AboutArrhythmia/About-Arrhythmia\\_UCM\\_002010\\_Article.jsp](http://www.heart.org/HEARTORG/Conditions/Arrhythmia/AboutArrhythmia/About-Arrhythmia_UCM_002010_Article.jsp). Accessed on March 4, 2020.**
2. **American Heart Association. Tachycardia. September 30, 2016. Available at: <https://www.heart.org/en/health-topics/arrhythmia/about-arrhythmia/tachycardia--fast-heart-rate>. Accessed on March 16, 2020.**
3. **American Heart Association. Ventricular fibrillation. September 30, 2016. Available at: <https://www.heart.org/en/health-topics/arrhythmia/about-arrhythmia/ventricular-fibrillation>. Accessed on March 16, 2020.**
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ENCORE

Premature Ventricular Contractions (PVC)

Ventricular Tachycardia (VT)

The use of specific product names is illustrative only. It is not intended to be a recommendation of one product over another, and is not intended to represent a complete listing of all products available.

Document History

Status	Date	Action
New	05/14/2020	Medical Policy & Technology Assessment Committee (MPTAC) review. Initial document development.

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