Anthem

# Medical Policy

**Subject:** Electrophysiology-Guided Noninvasive Stereotactic Cardiac Radioablation
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## Description/Scope

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

**Note**: For more information on the treatment of cardiac arrythmias, please see the following:

- CG-SURG-55 Cardiac Electrophysiological Studies (EPS) and Catheter Ablation

## 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) 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 the other for pericarditis. Of the 18 participants who survived 6 months to undergo a post-procedure assessment, the primary efficacy endpoint, reduction in VT episodes or PVC burden was achieved in 17/18 (94%) of participants. The median number of VT 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. The authors reported “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.

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 SBRT 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 system using radiation oncology and cardiac electrophysiology. First in-human studies of radioablation in the treatment of cardiac arrhythmias are being conducted in ongoing phase I/II trial (ENCORE-VT; NCT02919618). The estimated study enrollment is 19 participants and estimated completion date is January 2024. The CARA-VT RCT trial (Catheter Ablation Versus Radio-Ablation for Ventricular Tachycardia: A Randomized Controlled Trial; NCT05047198) began in February 2022. This phase 3 prospective, vanguard non-inferior trial is designed to compare the current standard of care, catheter ablation, for VT to stereotactic radiotherapy for non-invasively ablative VT using a novel non-invasive electrocardiogram-based body surface mapping technology. The study’s estimated enrollment is 244 participants, with an estimated completion in December 2027.

The current published evidence evaluating the use of SBRT as a viable alternative treatment of cardiac arrhythmias is limited to preliminary prospective or retrospective studies or case series (Aras, 2023; Carbucicchio, 2021; Gianni, 2020; Ninni, 2022). The clinical knowledge regarding this treatment is still in the early stage of development. 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.

## Background/Overview

According to the American Heart Association (2017), ventricular arrhythmia often is related to interference in the electrical conduction in the heart associated with 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, catheter ablation 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 SBRT 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.

The ability to treat an individual without the need for sedation and within a single outpatient session is one of the cited advantages of this proposed treatment. Early studies report that the procedure is generally well tolerated. However, the potential for radiation-associated toxicities both cardiac or in adjacent organs, and the long-term safety of the procedure is unknown. Pericarditis and pneumonitis are commonly reported early adverse effects. Radiation affects the heart in various ways, including the development of restrictive cardiomyopathy, valvular dysfunction, pericardial disease, vasculopathy or conduction dysfunction. Radiation therapy can adversely affect adjacent organs including the stomach, bowel, esophagus, lungs, bronchi, spinal cord and ribs (Hayase, 2022).

## 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.

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** | |
| 0745T | Cardiac focal ablation utilizing radiation therapy for arrhythmia; noninvasive arrhythmia localization and mapping of arrhythmia site (nidus), derived from anatomical image data (eg, CT, MRI, or myocardial perfusion scan) and electrical data (eg, 12-lead ECG data), and identification of areas of avoidance |
| 0746T | Cardiac focal ablation utilizing radiation therapy for arrhythmia; conversion of arrhythmia localization and mapping of arrhythmia site (nidus) into a multidimensional radiation treatment plan |
| 0747T | Cardiac focal ablation utilizing radiation therapy for arrhythmia; delivery of radiation therapy, arrhythmia |
| **ICD-10 Diagnosis** | |
| | All diagnoses |

## References

**Peer Reviewed Publications:**


1. Aras D, Çetin EHÖ, Ozturk HF, et al. Stereotactic body radioablation therapy as an immediate and early term antiarrhythmic palliative therapeutic choice in patients with refractory ventricular tachycardia. J Interv Card Electrophysiol. 2023; 66(1):135-143.
2. Carbucicchio C, Andreini D, Piperno G, et al. Stereotactic radioablation for the treatment of ventricular tachycardia: preliminary data and insights from the STRA-MI-VT phase Ib/II study. J Interv Card Electrophysiol. 2021; 62(2):427-439.
3. 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.
4. Gianni C, Rivera D, Burkhardt JD, et al. Stereotactic arrhythmia radioablation for refractory scar-related ventricular tachycardia. Heart Rhythm. 2020; 17(8):1241-1248.
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6. Kim EJ, Davogustto 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.
7. Krug D, Blanck O, Andratschke N, et al. Recommendations regarding cardiac stereotactic body radiotherapy for treatment refractory ventricular tachycardia. Heart Rhythm. 2021; 18(12):2137-2145.
8. 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.
9. Ninni S, Gallot-Lavallée T, Klein C, et al. Stereotactic radioablation for ventricular tachycardia in the setting of electrical storm. Circ Arrhythm Electrophysiol. 2022; 15(9):e010955.
10. 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.
11. 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 29, 2023.

**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. Ottawa Heart Institute Research Corporation. Catheter ablation versus radio-ablation for ventricular tachycardia: a randomized controlled trial (CARA-VT RCT). NLM Identifier: NCT05047198. Last updated December 12, 2022. Available at: https://clinicaltrials.gov/ct2/show/NCT05047198. Accessed on March 29, 2023.
3. 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 December 2, 2021. Available at: https://clinicaltrials.gov/ct2/show/NCT02919618. Accessed on March 29, 2023.

## Websites for Additional Information

1. American Heart Association. Arrhythmia. Available at: https://www.heart.org/en/health-topics/arrhythmia. Accessed on March 29, 2023.
2. American Heart Association. Tachycardia: Fast Heart Rate. Last reviewed: November 14, 2022. Available at: https://www.heart.org/en/health-topics/arrhythmia/about-arrhythmia/tachycardia--fast-heart-rate. Accessed on March 29, 2023.
3. American Heart Association. Ventricular fibrillation. Last reviewed November 15, 2022. Available at: https://www.heart.org/en/health-topics/arrhythmia/about-arrhythmia/ventricular-fibrillation. Accessed on March 29, 2023.
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## Index



**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 |
|---|---|---|
| Reviewed | 05/11/2023 | Medical Policy & Technology Assessment (MPTAC) review. Updated Description, Rationale, Background, References and Websites sections. |
| | 12/28/2022 | Updated Coding section with 01/01/2023 CPT changes; added 0745T, 0746T, 0747T replacing 77373, 77435, 77299, 77399 and related diagnosis codes (no longer applicable). |
| Reviewed | 05/12/2022 | MPTAC review. Updated Rationale, Background, References and Websites sections. |
| Reviewed | 05/13/2021 | MPTAC review. Updated Rationale, References and Websites sections. |
| New | 05/14/2020 | MPTAC review. Initial document development. |