HRS and ACC Joint Comment on Coverage for Pulsed Field Ablation

The Heart Rhythm Society (HRS) and the American College of Cardiology (ACC) are global leaders in science, education and transforming cardiovascular care and improving heart health for all. HRS represents more than 8,000 members in cardiac pacing and electrophysiology, a distinct specialty in cardiology. ACC is the professional home for the entire cardiovascular care team, with more than 56,000 members in 140 countries. HRS and ACC represent members committed to ensuring a world where science, knowledge and innovation optimize patient care and outcomes. Learn more at HRSonline.org and ACC.org.

Catheter ablation has emerged as a cornerstone therapy for the treatment of atrial fibrillation (AF) which is the most commonly encountered arrhythmia in clinical practice. In the past, thermal energy (using radiofrequency or cryoablation energy) has been utilized to ablate cardiac tissue for the treatment of AF and other arrhythmias. Recently, pulsed field ablation (PFA) has emerged as an alternative energy source for ablating cardiac tissue. Early studies demonstrated specific advantages for the use of PFA based on its cardiac tissue selectivity which reduces or eliminates the risk of injury to adjacent structures such as the esophagus or phrenic nerve. Since then, numerous studies have shown the safety and efficacy of PFA for the treatment of AF.

Over the past year, the FDA has approved the use of PFA using technology provided from two manufacturers on the strength of positive published clinical trial data. Specifically, the multinational PULSED AF study demonstrated that PFA had excellent safety and efficacy in the treatment of paroxysmal and persistent AF.[1] The ADVENT randomized clinical trial demonstrated that PFA was non-inferior to thermal ablation (radiofrequency and cryo) in safety and efficacy for the treatment of drug-refractory paroxysmal AF.[2] Recent sub-analysis for the ADVENT trial indicates PFA lowers recurrent post ablation AA burden.[3] Additionally, the MANIFEST-17K registry shows excellent safety and efficacy outcomes for PFA in the real-world setting measured over a two year window with over 17,000 patients.[4] The current PFA clinical trials follow-up of one year meets the standards of conventional study and matches those used for thermal ablation. Additionally, a pooled retrospective analysis of PFA showing 73% freedom from recurrence at five years is available.[5]

HRS and ACC believe that PFA should be made available to patients based on the best clinical judgement of the treating physician. Clinicians are best able to determine patient selection for PFA. The breadth of published clinical evidence with both clinical trial and real-world registry data indicates PFA is an effective modality of catheter ablation for AF with efficacy comparable to thermal-based ablation therapy and with a likely enhanced safety profile. HRS and ACC strongly recommend that payers apply the same coverage criteria for PFA as those established for thermal ablation in the treatment of AF. This gives clinicians the ability to choose technologies that are best suited for the individual patient.

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[1] (Verma A, 2023)
[2] (Reddy VU, 2023)
[3] (Reddy, Mansour, & Calkins, 2024)
[4] (Ekanem, Neuzil, & Reichlin, 2024)
[5] (Musikantow, Neuzil, Anic, & al, 2023)