

Position Statement

Pulsed-Field Ablation (PFA) for Treatment of Atrial Fibrillation

The Heart Rhythm Society (HRS) is the international leader in science, education and advocacy for cardiac arrhythmia professionals and patients, and the primary information resource on heart rhythm disorders. Its mission is to improve the care of patients by promoting research, education, and optimal health care policies and standards. HRS represents over 8,000 members in cardiac pacing and electrophysiology, consisting of physicians, scientists, and allied health care professionals. Electrophysiology is a distinct specialty of cardiology, with certification in cardiology, as well as eligibility for board certification in clinical cardiac electrophysiology through the American Board of Internal Medicine.

Historically, thermal energy (using radiofrequency or cryo ablation) has been used to ablate cardiac tissue in the treatment of various arrhythmias including atrial fibrillation (AF). Shortcomings of thermal ablation are well-known and can confer significant morbidity and mortality to patients. Available preclinical data has demonstrated that the cardiac tissue specificity of PFA spares adjacent structures such as the esophagus and phrenic nerve, thereby reducing the risks of an AF ablation procedure.

Several large prospective, multicenter, controlled clinical trials have investigated the safety and efficacy of PFA for the treatment of AF. Based on these pivotal clinical trials, PFA technologies have received FDA approval in the United States for treatment of AF. The multinational PULSED AF study¹ demonstrated that PFA had an excellent safety and efficacy profile in the treatment of paroxysmal and persistent AF. The U.S.-based ADVENT randomized clinical trial² demonstrated that PFA was non-inferior to thermal ablation (radiofrequency and cryo) in safety and efficacy for treatment of drug-refractory paroxysmal AF. The multinational MANIFEST-PF registry also demonstrated excellent safety and efficacy outcomes for PFA in the real-world setting.

In the context of regulatory approval of PFA by multiple competent authorities across the world (including the FDA), HRS believes that this novel treatment modality should be made available to patients based on the best clinical judgment of the treating physician. Controlled clinical trials and real-world evidence registries have demonstrated that PFA is a safe and effective treatment for arrhythmia conditions including AF. Adoption of this technology could lead to improved cardiovascular outcomes and quality of life with reduced costs associated with recurrent hospitalizations and the need for additional procedures. The Society recommends that payors apply the same coverage criteria for PFA as those established for thermal ablation of AF.

References

- ¹ Pulsed Field Ablation for the Treatment of Atrial Fibrillation: PULSED AF Pivotal Trial.
- Verma A, Haines DE, Boersma LV, Sood N, Natale A, Marchlinski FE, Calkins H, Sanders P, Packer DL, Kuck KH, Hindricks G, Onal B, Cerkvenik J, Tada H, DeLurgio DB; PULSED AF Investigators. Circulation. 2023 May 9;147(19):1422-1432.

^{2.} Pulsed Field or Conventional Thermal Ablation for Paroxysmal Atrial Fibrillation. Reddy VY, Gerstenfeld EP, Natale A, Whang W, Cuoco FA, Patel C, Mountantonakis SE, Gibson DN, Harding JD, Ellis CR, Ellenbogen KA, DeLurgio DB, Osorio J, Achyutha AB, Schneider CW, Mugglin AS, Albrecht EM, Stein KM, Lehmann JW, Mansour M; ADVENT Investigators. N Engl J Med. 2023 Nov 2;389(18):1660-1671.

³ Turagam MK, Neuzil P, Schmidt B, Reichlin T, Neven K, Metzner A et al. <u>Safety and effectiveness of pulsed field ablation to treat atrial</u> <u>fibrillation: one-year outcomes from the MANIFEST-PF registry. Circulation 2023;148:35–46.</u>