Coverage for the Extravascular Implantable Cardioverter-Defibrillator (EV-ICD)

On behalf the American College of Cardiology (ACC) and the Heart Rhythm Society (HRS), hereinafter referred to as the societies, we respectfully urge payers to include the extravascular implantable cardioverter-defibrillator (EV-ICD) in its ICD Medical Policy as a covered option for appropriately indicated patients. The societies recognize that payers share our commitment to coverage policies grounded in rigorous clinical evidence, patient safety, and the clinical judgment of the treating physician. We view this as an opportunity to partner with payers in ensuring that coverage keeps pace with the evolving evidence base, and we believe the data supporting the EV-ICD provide a strong foundation for that collaboration.

The ACC is the global leader dedicated to transforming cardiovascular care and improving heart health through education, research, quality improvement, clinical guidance, and advocacy on behalf of cardiovascular professionals and the patients they serve.

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. HRS represents more than 9,000 specialists in cardiac pacing and electrophysiology, consisting of physicians, scientists, and allied health care professionals.

EV-ICD: Considerations and Clinical Evidence Supporting Safety and Effectiveness versus Transvenous and Subcutaneous ICD systems

The safety and effectiveness of the EV-ICD have been well established, which promulgated FDA approval in October 2023. The EV-ICD abrogates vascular and endocardial lead-related risks while preserving the required therapeutic capabilities of a defibrillator. Substernal (versus transvenous) lead placement avoids the vasculature and intracardiac chambers, removing the risks of venous obstruction, lead-related tricuspid regurgitation, endocarditis, and the potential future need for transvenous lead extraction (1). The pivotal clinical trial, published in the *New England Journal of Medicine*, enrolled 316 patients with Class I or IIa ICD indications and demonstrated defibrillation success in 98.7% of patients at implantation, with freedom from major system- or procedure-related complications of 92.6% (1). Long-term follow-up through 3 years confirmed 100% defibrillation efficacy for spontaneous ventricular arrhythmias, successful anti-tachycardia pacing (ATP), and continued freedom from major complications (2).

Transvenous ICDs have been the standard of care for decades and remain life-saving devices. However, transvenous systems require endocardial leads that carry well-documented long-term risks. Young patients requiring decades of transvenous ICD therapy are disproportionately affected (3). Lead-related mechanical complications, including fracture,

insulation failure, and dislodgement, occur in up to 1 in 4 patients followed to 10 years in real-world data (1). Significant venous obstruction (>50% narrowing) develops in up to 30% of patients with indwelling leads, and complete venous occlusion occurs in approximately 10% (2). Lead-related tricuspid regurgitation affects 20-30% of patients with transvenous devices (5). Device infection, occurs approximately 1% per year, carrying a short-term mortality of 10-20% and frequently necessitates lead extraction, a procedure with major complication rates of 0.4-3.4% and a risk of death in up to 2% of patients (4). These risks compound with each subsequent device procedure. (6)

Unlike subcutaneous implantable cardioverter-defibrillators (S-ICDs), EV-ICDs have the capacity to deliver anti-tachycardia pacing (ATP). This therapeutic feature is standard in traditional transvenous ICD systems but is absent in the subcutaneous ICD (S-ICD), which also avoids the vasculature and heart. As such, the EV-ICD represents the singular non-transvenous platform capable of delivering both ATP and defibrillation therapies within a unified system (2). Furthermore, candidate selection for S-ICD implantation is limited by the necessity of a surface electrocardiographic screening protocol. Current clinical estimates indicate that **approximately 10%** of screened patients fail to meet the required morphology criteria for S-ICD eligibility. Given these constraints, the EV-ICD serves as a critical alternative therapeutic option for this patient population.

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EV-ICD: Regulatory, Reimbursement, and Appropriate Use Considerations

As previously noted, the EV-ICD received FDA approval in October 2023. It was included in the National Coverage Determination (NCD) for Implantable Cardioverter Defibrillators in April 2026, which mandates coverage for Medicare and Medicare Advantage beneficiaries. The device's current assignment to a Category III CPT code (0571T) reflects the AMA's standard process for tracking new technologies and does not indicate investigational or experimental status. EV-ICD procedures are assigned to the same MS-DRGs (275–277) and Comprehensive Ambulatory Payment Classification (C-APC 5232) as transvenous ICDs, subcutaneous ICDs, and CRT-D devices.

Finally, the 2025 ACC/AHA/ASE/HFSA/HRS/SCAI/SCCT/SCMR Appropriate Use Criteria for ICDs, CRT, and Pacing Expert Consensus Statement recognized the EV-ICD as a non-transvenous alternative offering ATP capabilities unavailable with other non-transvenous systems (9).

EV-ICD: Patient-Centered Clinical Considerations

a) Patient Comfort: ICD shocks are painful, psychologically distressing, and associated with anxiety, depression, and decreased quality of life. Transvenous ICDs mitigate this through ATP, which painlessly terminates the majority of monomorphic ventricular tachycardias before a shock is needed. The EV-ICD preserves this critical capability without requiring leads in the heart or vasculature. In the pivotal study, ATP from the extravascular space successfully terminated the majority of monomorphic VT episodes, sparing those patients from shocks (10). Patients treated with ATP alone experience hospitalization rates and healthcare costs equivalent to patients receiving no therapy at all, whereas patients receiving shocks incur significantly higher utilization and expenditures (11).

b) Patient Access: For patients with limited or compromised venous access, including those on hemodialysis, with prior device infections, and with congenital heart disease, the EV-ICD fills a critical unmet need by providing full ICD therapy without requiring vascular access.

c) Minimizing Long-term Complications: For younger patients facing decades of device therapy, the EV-ICD prevents vascular invasion and provides extended projected battery longevity reducing the number of generator replacements and the cumulative surgical risk that accompanies each procedure (12). Modeling data estimate 1.4 to 1.6 fewer replacement surgeries per patient over a lifetime, with a 24–26% reduction in long-term healthcare costs (12).

Formal Request for Policy Inclusion

The societies strongly advocate that payers apply consistent coverage criteria across all ICD modalities. This alignment empowers clinicians to select the specific technology best suited to individual patient needs. Towards that end, we respectfully request that updates of ICD Medical Policy to include the EV-ICD as a covered option for indicated patients. Clinicians are best positioned to determine the optimal ICD type for individual patients. The EV-ICD is FDA-approved, supported by peer-reviewed multicenter clinical data, incorporated into national coverage policy, and recognized within contemporary professional society guidance. Establishing coverage parity across all FDA-approved ICD systems ensures that clinical decisions can be executed without undue administrative barriers.

Thank you for your consideration. We welcome further dialogue and stand ready to provide any additional data required to support this policy update. Please contact Kristin Christensen (kchristensen@acc.org) or Lisa Miller (lmiller@hrsonline.org) with any questions.

References

1. Efficacy and Safety of an Extravascular Implantable Cardioverter–Defibrillator. Friedman P, Murgatroyd F, Boersma LVA, et al. The New England Journal of Medicine. 2022;387(14):1292-1302. doi:10.1056/NEJMoa2206485.
2. The Development of the Extravascular Defibrillator With Substernal Lead Placement: A New Frontier for Device-Based Treatment of Sudden Cardiac Arrest. Thompson AE, Atwater B, Boersma L, et al. Journal of Cardiovascular Electrophysiology. 2022;33(6):1085-1095. doi:10.1111/jce.15511.
3. Risk Factors and Temporal Trends of Complications Associated With Transvenous Implantable Cardiac Defibrillator Leads. Koneru JN, Jones PW, Hammill EF, Wold N, Ellenbogen KA. Journal of the American Heart Association. 2018;7(10):e007691. doi:10.1161/JAHA.117.007691.
4. Managing Implanted Cardiac Electronic Devices in Patients With Severe Tricuspid Regurgitation: JACC State-of-the-Art Review. Hahn RT, Wilkoff BL, Kodali S, et al. Journal of the American College of Cardiology. 2024;83(20):2002-2014. doi:10.1016/j.jacc.2024.02.045.
5. Complications Associated With Transvenous Cardiac Implantable Electronic Devices: Recognition and Management : A Narrative Review. Zimetbaum PJ, Ferro EG, Secemsky EA, Karchmer AW, Kramer DB. Annals of Internal Medicine. 2025;. doi:10.7326/ANNALS-25-02383.
6. 2017 HRS Expert Consensus Statement on Cardiovascular Implantable Electronic Device Lead Management and Extraction. Kusumoto FM, Schoenfeld MH, Wilkoff BL, et al. Heart Rhythm. 2017;14(12):e503-e551. doi:10.1016/j.hrthm.2017.09.001
7. Lead-Related Venous Obstruction in Patients With Implanted Cardiac Devices: JACC Review Topic of the Week. Zimetbaum P, Carroll BJ, Locke AH, Secemsky E, Schermerhorn M. Journal of the American College of Cardiology. 2022;79(3):299-308. doi:10.1016/j.jacc.2021.11.017.
8. The Development of the Extravascular Defibrillator With Substernal Lead Placement: A New Frontier for Device-Based Treatment of Sudden Cardiac Arrest. Thompson AE, Atwater B, Boersma L, et al. Journal of Cardiovascular Electrophysiology. 2022;33(6):1085-1095. doi:10.1111/jce.15511.
9. ACC/AHA/ASE/HFSA/HRS/SCAI/SCCT/SCMR 2025 Appropriate Use Criteria for Implantable Cardioverter-Defibrillators, Cardiac Resynchronization Therapy, and Pacing. Russo AM, Desai MY, Do MM, et al. Journal of the American College of Cardiology. 2025;85(11):1213-1285. doi:10.1016/j.jacc.2024.11.023.
10. Performance and Safety of the Extravascular Implantable Cardioverter Defibrillator Through Long-Term Follow-Up: Final Results From the Pivotal Study. Friedman P, Murgatroyd F, Boersma LVA, et al. Circulation. 2025;151(4):322-332. doi:10.1161/CIRCULATIONAHA.124.071795.
11. Increased Hospitalizations and Overall Healthcare Utilization in Patients Receiving Implantable Cardioverter-Defibrillator Shocks Compared With Antitachycardia Pacing. Sanders P, Connolly AT, Nabutovsky Y, Fischer A, Saeed

M. JACC. Clinical Electrophysiology. 2018;4(2):243-253. doi:10.1016/j.jacep.2017.09.004.

12. The Clinical and Economic Impact of Extended Battery Longevity of a Substernal Extravascular Implantable Cardioverter Defibrillator. Knight BP, Clémenty N, Amin A, et al. Journal of Cardiovascular Electrophysiology. 2024;35(2):230-237. doi:10.1111/jce.16150.