Regence

Medical Policy Manual Surgery, Policy No. 17

Extravascular (Substernal) Implantable Cardioverter-Defibrillator

Effective: August 1, 2025

Next Review: June 2026
Last Review: June 2025

IMPORTANT REMINDER

Medical Policies are developed to provide guidance for members and providers regarding coverage in accordance with contract terms. Benefit determinations are based in all cases on the applicable contract language. To the extent there may be any conflict between the Medical Policy and contract language, the contract language takes precedence.

PLEASE NOTE: Contracts exclude from coverage, among other things, services or procedures that are considered investigational or cosmetic. Providers may bill members for services or procedures that are considered investigational or cosmetic. Providers are encouraged to inform members before rendering such services that the members are likely to be financially responsible for the cost of these services.

DESCRIPTION

The extravascular implantable cardioverter-defibrillator (EV-ICD) system is a non-transvenous alternative to other commercially available ICD systems. EV-ICD provides defibrillation and pacing therapies utilizing leads located on the anterior mediastinum (substernal).

MEDICAL POLICY CRITERIA

The use of an extravascular (substernal) implantable cardioverter defibrillator is considered **investigational** for all indications.

NOTE: A summary of the supporting rationale for the policy criteria is at the end of the policy.

CROSS REFERENCES

1. New and Emerging Medical Technologies and Procedures, Medicine, Policy No. 149
2. Intracardiac Ischemia Monitoring, Surgery, Policy No. 208
3. Dual Chamber Leadless Cardiac Pacemakers, Surgery, Policy No. 217

BACKGROUND

An implantable cardioverter-defibrillator (ICD) is a device designed to monitor an individual's

heart rate, recognize ventricular fibrillation (VF) or ventricular tachycardia (VT), and deliver an electric shock to terminate these arrhythmias to reduce the risk of sudden death. ICD systems without transvenous access were developed as an alternative to a transvenous ICD (T-ICD) to reduce lead-related complications. A subcutaneous ICD (S-ICD) uses a subcutaneous electrode implanted adjacent to the left sternum. The electrodes sense the cardiac rhythm and deliver countershocks through the subcutaneous tissue of the chest wall.

In an extravascular ICD (EV-ICD), the lead is placed substernally at the anterior mediastinum, and the pulse generator is placed at the left midaxillary region. The pulse generator size and energy capacity are similar to T-ICD devices, which addresses some of the limitations of S-ICD devices. However, EV-ICD still have a risk of cardiac injury or perforation.

REGULATORY STATUS

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) granted premarket approval (PMA) for the Aurora EV-ICD™ System (Medtronic, Inc) in October 2023. [1] This device is indicated for the automated treatment of patients who have experienced, or are at significant risk of developing, life-threatening ventricular tachyarrhythmias through the delivery of anti- tachycardia pacing, cardioversion, and defibrillation therapies.

Medical conditions that may indicate a patient for an EV-ICD for primary or secondary prevention of sudden cardiac death due to life-threatening ventricular tachyarrhythmias include:

- Previous ventricular tachyarrhythmias
- Coronary disease with left ventricular dysfunction
- Cardiomyopathy
- Inherited primary arrhythmia syndromes
- Congenital heart disease.

The Aurora EV-ICD™ System was approved by the FDA for patients who are at risk of life-threatening ventricular arrhythmias and have not had a prior sternotomy and do not need pacing.

EVIDENCE SUMMARY

Friedman (2025) conducted a 3-year follow-up of a prospective, nonrandomized global clinical study on patients with EV-ICDs.[2] The results showed that all shock therapies for spontaneous ventricular arrhythmias were 100% successful (27/27). However, the inappropriate shock rate rose to 17.5%, primarily due to P-wave oversensing. Freedom from system- or procedure-related major complications was 89%, with lead dislodgment (n = 9) and infections (n = 8) being the most common complications.

Crozier (2023) published a 3-year update for the first-in-human pilot study that examined the use of EV-ICD with the aim of reducing mortality in patients who are at risk of sudden cardiac death.[3] The original study extended to 35 patients, with 14 completing the 3-year follow-up, and 10 of those 14 having chronic X-rays that allowed for chronic lead motion analysis. Of the 35 patients, 3 patients elected for a system removal. Overall, 7/10 of patients with chronic X-rays had stable lead positioning with two patients experiencing minimal lead movement and one patient experiencing larger lead movement. It is reported that there were two inappropriate shocks related to environmental interference, and one appropriate shock due to P-wave

oversensing. No other patients experienced a ventricular arrhythmia requiring intervention from the EV-ICD device.

Friedman (2022) published a prospective, nonrandomized, global clinical study in patients who received an EV-ICD.[4] All patients had a class I or IIa indication for ICD placement (81.6% for primary prevention, 18.0% for secondary prevention). At baseline, 83.9% had cardiomyopathy, 42.7% had ventricular arrhythmias, and 13.9% had atrial fibrillation. The primary efficacy endpoint was successful defibrillation at implantation, and safety was assessed for 6 months. Of the entire study population (N=356), 302 patients were successfully defibrillated after ventricular arrhythmia was induced; 98.7% of these patients had successful defibrillation. At 6 months, 92.6% of patients had not experienced a major complication. Major complications occurred in 23 patients, none of which had further sequelae. Inappropriate shocks (n=118) occurred in 29 patients during follow-up (median number of shocks per patient, 2). The most common reasons for inappropriate shocks were P-wave oversensing (34 episodes) and lead noise (19 episodes).

Crozier (2020) conducted the first-in-human pilot study characterizing the safety of the EV-ICD system and implant procedure as well as examining the effectiveness of defibrillation, sensing, and pacing.[5] A total of 20 participants completed the procedure across Australia and New Zealand and participants were assessed at 1 day post, 2 weeks, 4-6 weeks, and at 3 months. Induced ventricular arrhythmias were terminated in 90% of patients and pacing capture was achieved in 95% of patients. Further research is needed to identify the long-term safety and benefit of the device.

Summary

For individuals who need an ICD who receive an extravascular ICD (EV-ICD), the evidence includes nonrandomized studies. Relevant outcomes are overall survival, morbid events, quality of life, and treatment-related mortality and morbidity. The largest available study with an EV-ICD reported high rates of defibrillation after implantation and a low rate of major complications, with a numerically similar rate of inappropriate shocks compared to studies with Transvenous-ICD and Subcutaneous-ICD. The major limitation of the research is the lack of an active control group. Studies have not compared Aurora with other ICDs, and outcomes are not reported for more than three-year follow-up. The evidence is insufficient to determine that this technology results in an improvement in the net health outcome.

PRACTICE GUIDELINES

HEART RHYTHM SOCIETY, EUROPEAN HEART RHYTHM ASSOCIATION AND ASIA PACIFIC HEART RHYTHM SOCIETY POSITION PAPER (2022)

The Heart Rhythm Society, in conjunction with the European Heart Rhythm Association and the Asia Pacific Heart Rhythm Society published a position paper on several cardiac devices.[6] The position paper mentions extravascular ICDs but did not provide any formal recommendations regarding their use due to a lack of available data.

SUMMARY

There is not enough research to show that extravascular implantable cardioverter

defibrillators (EV-ICDs), also known as substernal ICDs, improve health outcomes compared to traditional transvenous or subcutaneous ICDs. Also, no evidence-based guidelines recommend the use of extravascular ICDs. Therefore, the use of EV-ICDs is considered investigational for all indications.

REFERENCES

1. Food and Drug Administration Premarket approval application (PMA) for the Aurora EV-ICD™ System- P220012. [cited 6/2/2025]. 'Available from:' https://www.accessdata.fda.gov/cdrh_docs/pdf22/P220012A.pdf.
2. Friedman P, Murgatroyd F, Boersma LVA, et al. Performance and Safety of the Extravascular Implantable Cardioverter Defibrillator Through Long-Term Follow-Up: Final Results From the Pivotal Study. *Circulation.* 2025;151(4):322-32. PMID: 39327797
3. Crozier I, Haqqani H, Kotschet E, et al. Three-year chronic follow-up from the pilot study of a substernal extravascular implantable cardioverter-defibrillator. *Europace.* 2023;25(10). PMID: 37847230
4. Friedman P, Murgatroyd F, Boersma LVA, et al. Efficacy and Safety of an Extravascular Implantable Cardioverter-Defibrillator. *N Engl J Med.* 2022;387(14):1292-302. PMID: 36036522
5. Crozier I, Haqqani H, Kotschet E, et al. First-in-Human Chronic Implant Experience of the Substernal Extravascular Implantable Cardioverter-Defibrillator. *JACC Clinical electrophysiology.* 2020;6(12):1525-36. PMID: 33213813
6. Boersma LV, El-Chami M, Steinwender C, et al. Practical considerations, indications, and future perspectives for leadless and extravascular cardiac implantable electronic devices: a position paper by EHRA/HRS/LAHRS/APHRS. *Europace.* 2022;24(10):1691-708. PMID: 35912932

CODES

Codes	Number	Description
CPT	0571T	Insertion or replacement of permanent implantable cardioverter defibrillator system, with substernal electrode(s), including all imaging guidance defibrillation threshold evaluation, induction of arrhythmia, evaluation of sensing for arrhythmia termination, and programming or reprogramming of sensing or therapeutic parameters, when performed
	0572T	Insertion of substernal implantable defibrillator electrode
	0573T	Removal of substernal implantable defibrillator electrode
	0574T	Repositioning of previously implanted extravascular substernal implantable defibrillator-pacing electrode
	0575T	Programming device evaluation (in person) of implantable cardioverter defibrillator system with substernal electrode, with iterative adjustment of the implantable device to test the function of the device and select optimal permanent programmed values with analysis, review and report by a physician or other qualified health care professional
	0576T	Interrogation device evaluation (in person) of implantable cardioverter defibrillator system with substernal electrode, with analysis, review and report by a physician or other qualified health care professional, includes connection, recording and disconnection per patient encounter

Codes	Number	Description
	0577T	Electrophysiologic evaluation of implantable cardioverter defibrillator system with substernal electrode (includes defibrillation threshold evaluation, induction of arrhythmia, evaluation of sensing for arrhythmia termination, and programming or reprogramming of sensing or therapeutic parameters)
	0578T	Interrogation device evaluation(s) (remote), up to 90 days, substernal lead implantable cardioverter defibrillator system w/interim analysis, review(s) and report(s) by a physician or other qualified health care professional
	0579T	Interrogation device evaluation(s) (remote), up to 90 days, substernal lead implantable cardioverter defibrillator system, remote data acquisition(s), receipt of transmissions and technician review, technical support and distribution of results
	0580T	Removal of substernal implantable defibrillator pulse generator only
	0614T	Removal and replacement of substernal implantable defibrillator pulse generator
HCPCS	None	

Date of Origin: *June 2025*