NOTE: This policy version is not effective until November 1, 2025.

Medicare Advantage Policy Manual **Policy ID:** M-SUR17

Extravascular (Substernal) Implantable Cardioverter-Defibrillator

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IMPORTANT REMINDER

The Medicare Advantage Medical Policy manual is not intended to override the member Evidence of Coverage (EOC), which defines the insured's benefits, nor is it intended to dictate how providers are to practice medicine. Physicians and other health care providers are expected to exercise their medical judgment in providing the most appropriate care for the individual member.

The Medicare Advantage Medical Policies are designed to provide guidance regarding the decision-making process for the coverage or non-coverage of services or procedures in accordance with the member EOC and the Centers of Medicare and Medicaid Services (CMS) policies, when available. In the event of a conflict, applicable CMS policy or EOC language will take precedence over the Medicare Advantage Medical Policy. In the absence of CMS guidance for a requested service or procedure, the health plan may apply their Medical Policy Manual or MCG™ criteria, both of which are developed with an objective, evidence-based process using scientific evidence, current generally accepted standards of medical practice, and authoritative clinical practice guidelines.

Medicare and EOCs exclude from coverage, among other things, services or procedures considered to be investigational, cosmetic, or not medically necessary, and in some cases, providers may bill members for these non-covered services or procedures. Providers are encouraged to inform members in advance when they may be financially responsible for the cost of non-covered or excluded 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).

MEDICARE ADVANTAGE POLICY CRITERIA

Note: This policy only addresses extravascular implantable cardioverter-defibrillators.

CMS Coverage Manuals	May be covered if performed as part of an approved Investigational Device Exemption (IDE) study. See references for link to M-MED150 Medicare-approved IDE studies.
National Coverage Determinations (NCDs)	None

Noridian Healthcare Solutions (Noridian) Local Coverage Determinations (LCDs) and Articles	None
Medical Policy Manual	*Medicare coverage guidance is not available for extravascular Implantable Cardioverter-defibrillators for any indication when not part of an approved IDE study.* Therefore, the health plan's medical policy is applicable. Extravascular (Substernal) Implantable Cardioverter-Defibrillator, Surgery, Policy No. 17 *(see "NOTE" below)*

NOTE: If a procedure or device lacks scientific evidence regarding safety and efficacy because it is investigational or experimental, the service is noncovered as not reasonable and necessary to treat illness or injury. (*Medicare IOM Pub. No. 100-04, Ch. 23, §30 A*). According to Title XVIII of the Social Security Act, §1862(a)(1)(A), only medically reasonable and necessary services are covered by Medicare. In the absence of a NCD, LCD, or other coverage guideline, CMS guidelines allow a Medicare Advantage Organization (MAO) to make coverage determinations, applying an ***objective, evidence-based process, based on authoritative evidence***. (*Medicare IOM Pub. No. 100-16, Ch. 4, §90.5*). The Medicare Advantage Medical Policy - Medicine Policy No. M-149 - provides further details regarding the plan's evidence-assessment process (see Cross References).

POLICY GUIDELINES

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. [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.

CROSS REFERENCES

Clinical Trials and Investigational Device Exemption (IDE) Studies, Medicine, Policy No. M-150
Intracardiac Ischemia Monitoring, Surgery, Policy No. M-208

REFERENCES

1. Decision Memo for Implantable Cardioverter Defibrillators (CAG-00157R4)
2. Medicare Approved Investigational Device Exemption (IDE) Studies
3. Medicare Approved Facilities/Trials/Registries ICD Registry
4. ClinicalTrials.gov ICD Registry
5. Medicare Claims Processing Manual, Chapter 32 – Billing Requirements for Special Services, 270 – Claims Processing for Implantable Automatic Defibrillator and 270.2 – Billing Requirements for Patients Enrolled in a Data Collection System
6. Food and Drug Administration Premarket approval application (PMA) for the Aurora EV-ICD™ System- P220012
7. Medicare Claims Processing Manual, Change Request 11605 – Transmittal 4513, section 19: Extravascular Implantable Cardioverter Defibrillator (EV-ICD)

CODING

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
	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)

Codes	Number	Description
	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	

***IMPORTANT NOTE:** Medicare Advantage medical policies use the most current Medicare references available at the time the policy was developed. Links to Medicare references will take viewers to external websites outside of the health plan's web control as these sites are not maintained by the health plan.*