

MEDICAL POLICY

Medical Policy Title	Implantable Cardioverter Defibrillator (ICD)
Policy Number	7.01.06
Current Effective Date	June 15, 2026
Next Review Date	February 2027

Our medical policies are guides to evaluate technologies or services for medical necessity. Criteria are established through the assessment of evidence based, peer-reviewed scientific literature, and national professional guidelines. Federal and state law(s), regulatory mandates and the member's subscriber contract language are considered first in the determination of a covered service.

(Link to [Product Disclaimer](#))

POLICY STATEMENT(S)

Primary Prevention

Ischemic Cardiomyopathy

- I. Implantable Cardiac Defibrillator (ICD) is **medically necessary** for primary preventions of sudden cardiac death (SCD) associated with ischemic cardiomyopathy in the setting of **ANY** of the following:
 - A. Post-acute myocardial infarction (MI) (less than or equal to 40 days) and **any** of the following when indication specific criteria are met:
 1. Left ventricular ejection fraction (LVEF) less than or equal to 30% in the setting of **either** of the following:
 - a. Complete revascularization after MI with percutaneous coronary intervention (PCI) or coronary artery bypass grafting (CABG) and **all** of the following:
 - i. Asymptomatic non-sustained ventricular tachycardia (NSVT) (greater or equal to 4 days post-MI);
 - ii. Electrophysiology studies (EPS) with inducible VT; **and**
 - iii. EPS performed after revascularization and less than 40 days post MI;
 - or**
 - b. Obstructive CAD not amenable to revascularization with **both** of the following:
 - i. Asymptomatic NSVT (greater than or equal to 4 days post-MI); **and**
 - ii. EPS with inducible sustained VT (EPS performed within 40 days of MI); **or**
 2. LVEF 31% to 40% when **both** of the following are met:
 - a. Asymptomatic NSVT (greater than or equal to 4 days post-MI); **and**
 - b. EPS with inducible sustained VT (if revascularized, EPS performed after revascularization, within 40 days of MI); **or**

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3. Pre-existing chronic cardiomyopathy (greater than or equal to three (3) months) with **either** of the following:
 - a. LVEF less than or equal to 30% due to old infarction with functional class I-III; **or**
 - b. LVEF less than or equal to 35% with NYHA functional class II-III;
- B. Post MI (greater than 40 days) with **any** of the following conditions:
 1. LVEF less than or equal to 35% and **both** of the following:
 - a. NYHA functional class I, II, or III; **and**
 - b. No PCI/CABG within three (3) months; **or**
 2. LVEF 36%-40% with **all** of the following:
 - a. No PCI/CABG within three (3) months;
 - b. Asymptomatic NSVT; **and**
 - c. EPS with inducible sustained VT; **or**
 3. PCI or CABG (less than or equal to three (3) months) with LVEF less than or equal to 35% on optimal medical therapy (OMT) for greater than or equal to three (3) months prior to PCI/CABG;
- C. Ischemic cardiomyopathy with LVEF less than or equal to 35% and **either** of the following:
 1. Individual has completed greater than or equal to three (3) months of OMT; **or**
 2. Individual has completed less than three (3) months of OMT with **either** of the following findings:
 - a. NSVT; **or**
 - b. EPS with inducible sustained VT.

Post MI need for Pacemaker Therapy

- II. ICD implantation is considered **medically necessary** in individuals with ischemic cardiomyopathy and a need for post-MI pacemaker therapy when **BOTH** of the following indications are met:
 - A. LVEF less than or equal to 35% in the setting of **either** of the following:
 1. Individual is post-acute MI (less than or equal to 40 days); **or**
 2. Individual is post MI (greater than 40 days) with PCI or CABG (greater than or equal to three (3) months);
- AND**
- B. Meets criteria for implantation of a pacemaker (see policy 7.01.58 for pacemaker criteria) for **any** of the following indications:

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1. Sinus node dysfunction;
2. Atrioventricular block (AVB);
3. Conduction disorders with 1:1 atrioventricular conduction;
4. Recurrent syncope;
5. Peri-procedural and post operative indications; **or**
6. Neuromuscular diseases known to involve the heart.

Non-Ischemic Cardiomyopathy

III. ICD implantation is considered **medically necessary** for primary prevention of SCD associated with non-ischemic cardiomyopathy for **ANY** of the following indications:

- A. Idiopathic non-ischemic cardiomyopathy when **all** of the following are met:
 1. LVEF less than or equal to 35% after greater than or equal to three (3) months of OMT
 2. Age less than or equal to 85 years; **and**
 3. Functional NYHA class I-III;
- B. Non-ischemic cardiomyopathy with recent valve or TAVR (within three (3) months) with **both** of the following:
 1. LVEF less than or equal to 35%; **and**
 2. Need for pacemaker and LV function unlikely to improve;
- C. Non-ischemic cardiomyopathy from other specific etiologies that have received greater than or equal to three (3) months of OMT in the setting of **any** of the following conditions:
 1. Giant-cell myocarditis regardless of the LVEF; **or**
 2. LVEF less than or equal to 35% with **any** of the following conditions:
 - a. Sarcoid heart disease, no MRI performed;
 - b. Myotonic dystrophy;
 - c. Chagas disease; **or**
 - d. Peripartum cardiomyopathy with **all** of the following:
 - i. Less than three (3) months postpartum; **and**
 - ii. LVEF persists less than or equal to 35% postpartum; **or**
 3. Genetic conditions with structural heart disease including **any** of the following:
 - a. Hypertrophic cardiomyopathy (HCM) with **one (1) or more** of the following risk factors:
 - i. LV wall thickness greater than or equal to 30mm;

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- ii. One (1) or more episodes of unexplained syncope within the preceding six (6) months;
- iii. SCD in one or more first-degree relatives presumably caused by HCM;
- iv. Spontaneous NSVT; **or**
- v. Abnormal blood pressure response with exercise; **or**
- b. Arrhythmogenic right ventricular dysplasia/cardiomyopathy; **or**
- c. Evidence of structural cardiac disease with Lamin A/C mutation or other genetic ACM with LVEF less than or equal to 45%; **or**
- 4. In individuals without structural heart disease with **either** of the following genetic conditions:
 - a. Catecholaminergic Polymorphic VT with **both** of the following:
 - i. NSVT; **and**
 - ii. Not tolerating medical therapy or breakthrough non-sustained ventricular arrhythmia on medical therapy; **or**
 - b. Brugada by ECG (Type I ECG Pattern) with inducible VT or VF at EPS.

Pre- or Post Heart Transplant

IV. ICD implantation is **medically necessary** for primary prevention of SCD for **EITHER** of the following indications:

- A. Individual is on a waiting list for heart transplant (outpatient status);
- B. Individual is post-heart transplant with multiple episodes of cellular or antibody mediated rejection.

Secondary Prevention

V. ICD may be considered **medically appropriate** for **ANY** of the following indications:

Cardiac Arrest Survivors

- A. Cardiac arrest from hemodynamically unstable or sustained VT, polymorphic VT, ventricular fibrillation (VF) for **any** of the following indications:
 - 1. Associated with any acute (less than 48 Hours) MI with **both** of the following conditions:
 - a. Obstructive coronary artery disease (CAD) with coronary anatomy not amenable to revascularization; **and**
 - b. EF less than or equal to 35%; **or**
 - 2. Associated with any acute (greater than 48 Hours) post-coronary revascularization when **both** of the following conditions exist:

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- a. No evidence for acute coronary occlusion, restenosis, acute infarct, or other clearly reversible cause; **and**
 - b. LVEF less than or equal to 35%; **or**
 3. Associated with coronary artery disease with **both** of the following conditions:
 - a. No recent MI (less than or equal to 40 days) prior to arrest; **and**
 - b. No recent coronary revascularization (less than or equal to three (3) months) prior to arrest; **or**
 4. During exercise testing when cardiac catheterization performed after arrest results for **any** of the following indications:
 - a. Significant CAD not amenable to revascularization;
 - b. Significant CAD identified and complete revascularization performed; **or**
 - c. Significant CAD identified and incomplete revascularization performed; **or**
 5. Not associated with coronary artery disease in the setting of **any** of the following conditions:
 - a. Non-ischemic dilated cardiomyopathy;
 - b. Myocardial sarcoidosis; **or**
 - c. Giant-cell myocarditis; **or**
- B. Cardiac arrest with idiopathic VF and a normal EF (greater than or equal to 50%) when no reversible causes have been identified including **all** of the following:
1. Pharmacologically induced sustained VT/VF;
 2. Sustained VT/VF with hypokalemia; **and**
 3. Wolff-Parkinson-White (WPW) syndrome with VT/VF and successfully ablated pathway.

Sustained VT/VF

- C. Sustained VT or VF and **either** of the following conditions:
1. Genetic disease associated with sustained VT/VF and a normal EF (greater than or equal to 50%) including **any** of the following:
 - a. Congenital long QT syndrome;
 - b. Short QT syndrome;
 - c. Catecholaminergic polymorphic VT;
 - d. Brugada syndrome;
 - e. Arrhythmogenic Right Ventricular Cardiomyopathy (ARVC); **or**
 - f. Hypertrophic cardiomyopathy; **or**

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2. Sustained hemodynamically stable monomorphic VT associated with structural heart disease (CAD with prior MI or non-ischemic dilated cardiomyopathy) and **all** of the following are met:
 - a. All inducible VT's are successfully ablated;
 - b. EF is less than or equal to 35%; **and**
 - c. Any identified bundle branch re-entry has been successfully ablated.

Syncope

- D. Unexplained syncope in an individual with **any** of the following conditions:
 1. Long QT syndrome in an individual on beta blocker therapy;
 2. Brugada pattern on electrocardiogram (ECG);
 3. Catecholaminergic polymorphic VT in an individual on a beta blocker;
 4. Coronary artery disease with prior MI in the setting or **either** of the following:
 - a. LVEF 36%-49% and **both** of the following:
 - i. No acute MI (less than or equal to 40 days); **and**
 - ii. Inducible sustained VT/VF on EP study; **or**
 - b. Ejection fraction less than or equal to 35%; **or**
 5. Non-ischemic structural heart disease with **any** of the following:
 - a. LV hypertrophy with EF less than or equal to 35%;
 - b. Non-ischemic dilated cardiomyopathy with EF less than or equal to 35%;
 - c. LV non-compaction with EF less than 50%;
 - d. Tetralogy of Fallot with prior corrective surgery;
 - e. Hypertrophic cardiomyopathy; **or**
 - f. Arrhythmogenic Right Ventricular Cardiomyopathy (ARVC).

VI. Subcutaneous ICD are considered **medically appropriate** for:

- A. Patients who have met the criteria for ICD implantation and who meet **ALL** of the following criteria:
 1. Have a contraindication to a transvenous ICD due to **one (1) or more** of the following:
 - a. Lack of adequate vascular access;
 - b. Compelling reason to preserve existing vascular; **or**
 - c. History of need for explanation of a transvenous ICD due to a complication, with ongoing need for ICD therapy; **and**

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- B. Has no indication for anti-bradycardia pacing; **and**
- C. Do not have ventricular arrhythmias that are known or anticipated to respond to anti-tachycardia pacing.

VII. ICDs are considered **not medically necessary** for **any** of the following indications:

- A. Incessant VT or VF: Defined as hemodynamically stable VT or VF continuing for hours;
- B. VF or VT is due to a reversible cause such as:
 - 1. Severe electrolyte disturbance;
 - 2. Drug induced torsades de pointes (TdP); **or**
 - 3. Acute, re-perfused MI with preserved ejection fraction; **or**
- C. Ablation candidate with no structural heart disease.

VIII. Substernal implantable cardioverter-defibrillator systems are considered **investigational**.

RELATED POLICIE(S)

Corporate Medical Policy

- 1.01.42 Home Automatic External Defibrillators (AEDs) and Wearable Cardioverter Defibrillators (WCDs)
- 7.01.58 Permanent Pacemakers and Cardiac Resynchronization Therapy (CRT) Devices
- 7.01.91 Heart Failure Management Devices
- 11.01.03 Experimental or Investigational Services

POLICY GUIDELINE(S)

- I. When an ICD is to be implanted, there should first be a consultation with an electrophysiologist.
- II. Case reports have indicated that transcutaneous electrical nerve stimulators (TENS) have been known to interfere with ICDs and pacemakers.
- III. Optimal medical therapy includes three (3) months of **ALL** of the following:
 - A. Beta-blocker;
 - B. Mineralcorticoid antagonist (MRA); **and**
 - C. **One (1)** of the following:
 - 1. ACE inhibitor;
 - 2. Angiotensin II receptor blocker; **or**
 - 3. Angiotensin receptor-neprilysin inhibitor.
- IV. New York Heart Association (NYHA) Heart Failure Definitions

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- Class I- No limitation of physical activity. Ordinary physical activity does not cause undue fatigue, palpitation, or dyspnea.
- Class II- Slight limitation of physical activity. Comfortable at rest. Ordinary physical activity results in fatigue, palpitation, or dyspnea.
- Class III- physical activity. Comfortable at rest. Less than ordinary activity causes fatigue, palpitation, or dyspnea.
- Class IV- Unable to carry on any physical activity without discomfort. Symptoms of heart failure may be present even at rest. If any physical activity is undertaken, discomfort is increased.

DESCRIPTION

An ICD is an electronic device designed to monitor a patient's heart rate, recognize VF or VT, and deliver an electronic shock to terminate these life-threatening arrhythmias. Indications for ICD implantation can be broadly subdivided into:

- Secondary prevention, e.g., for use in patients who have survived a prior sudden cardiac arrest or sustained VT; or
- Primary prevention or as a prophylactic, e.g., for use in patients with ischemic or nonischemic dilated cardiomyopathy or documented familial or inherited conditions, who are considered at high risk for sudden cardiac death, but who have not yet experienced life-threatening VT, VF or cardiac arrest.

While traditional ICDs have been used in the management of symptomatic and/or inducible VT and VF, technology has led to the development of a dual-chamber ICD that utilizes a sophisticated algorithm to detect and treat episodes of VT, VF, and, additionally, atrial fibrillation (AF). The prevention and treatment of AF focus, first, on maintaining or restoring sinus rhythm (SR), and then on controlling rate and preventing thromboembolic events.

ICDs may be combined with biventricular pacing, to treat symptoms of advanced heart failure in certain patients who already need an ICD. These devices combine an ICD with CRT. The defibrillator component detects and treats life-threatening heart rhythms. The CRT component coordinates the beating of the left and right ventricles of the heart, so that they work together more effectively to pump blood throughout the body.

The subcutaneous ICD (subq-ICD) was developed to avoid some of the complications arising from using a traditional ICD. The subq-ICD consists of a dedicated external programmer, a subcutaneous pulse generator enclosed in a titanium case, and a single subcutaneous electrode containing both sensing and defibrillating components. The device uses proprietary algorithms to detect ventricular arrhythmias and can deliver a pulse of 80 J. Subq-ICDs are limited by the large size, inability to provide anti-tachycardia pacing, limited bradycardia pacing support, and a higher shock that must be delivered, compared to transvenous ICDs. The device was approved as defibrillation therapy for patients with life-threatening ventricular tachyarrhythmias who have not had symptomatic bradycardia, continual ventricular tachycardia, or spontaneous, frequently recurring VT that can be

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terminated with anti-tachycardia pacing.

The substernal or extravascular ICD has been proposed as an alternative to the subq-ICD. The lead is placed under the sternum in the substernal space (anterior mediastinum) for pacing and defibrillation. The placement allows for a lower energy to capture and defibrillate the heart, compared to a subcutaneous lead. There are clinical trials and studies underway to determine the usefulness of this approach for lead placement.

AHA/ACC 2020 Established Clinical Risk Factors for HCM Sudden Death Risk Stratification:

Family history of sudden death from HCM	Sudden death judged definitively or likely attributable to HCM in ≥ 1 first-degree or close relatives who are ≤ 50 y of age. Close relatives would generally be second-degree relatives; however, multiple SCDs in tertiary relatives should also be considered relevant.
Massive Left Ventricular Hypertrophy (LVH)	Wall thickness ≥ 30 mm in any segment within the chamber by echocardiography or CMR imaging; consideration for this morphologic marker is also given to borderline values of ≥ 28 mm in individual patients at the discretion of the treating cardiologist. For pediatric patients with HCM, an absolute or z-score threshold for wall thickness has not been established; however, a maximal wall that corresponds to a z-score ≥ 20 (and > 10 in conjunction with other risk factors) appears reasonable.
Unexplained syncope	≥ 1 Unexplained episodes involving acute transient loss of consciousness, judged by history unlikely to be of neurocardiogenic (vasovagal) etiology, nor attributable to LV out flow tract obstruction (LVOTO), and especially when occurring within 6 months of evaluation (events beyond 5 y in the past do not appear to have relevance).
HCM with LV systolic dysfunction	Systolic dysfunction with EF $< 50\%$ by echocardiography or CMR imaging.
LV apical aneurysm	Apical aneurysm defined as a discrete thin-walled dyskinetic or akinetic segment of the most distal portion of the LV chamber; independent of size.
Extensive LGE on CMR imaging	Diffuse and extensive LGE, representing fibrosis, either quantified or estimated by visual inspection, comprising $\geq 15\%$ of LV mass (extent of LGE conferring risk has not been established in children).
Non-sustained VT (NSVT) on ambulatory monitor	It would seem most appropriate to place greater weight on NSVT as a risk marker when runs are frequent (≥ 3), longer (≥ 10 beats), and faster (≥ 200 bpm) occurring usually over 24 to 48 h of monitoring. For pediatric patients, a VT rate that exceeds the baseline sinus rate by $> 20\%$ is considered significant.

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SUPPORTIVE LITERATURE

Knops et al (2022) conducted the PRAETORIAN trial (A Prospective, Randomized Comparison of Subcutaneous and Transvenous Implantable Cardioverter Defibrillator Therapy) showed noninferiority of subcutaneous implantable cardioverter defibrillator (S-ICD) compared with transvenous implantable cardioverter defibrillator (TV-ICD) regarding inappropriate shocks and complications. In contrast to TV-ICD, S-ICD cannot provide anti-tachycardia pacing for monomorphic ventricular tachycardia. This prespecified secondary analysis evaluates the appropriate therapy and whether anti-tachycardia pacing reduces the number of appropriate shocks. The PRAETORIAN trial was an international, investigator-initiated randomized trial that included patients with an indication for implantable cardioverter defibrillator (ICD) therapy. Patients with previous ventricular tachycardia <170 bpm or refractory recurrent monomorphic ventricular tachycardia were excluded. In 39 centers, 849 patients were randomized to receive an S-ICD (n=426) or TV-ICD (n=423) and were followed for a median of 49.1 months. ICD programming was mandated by protocol. Appropriate ICD therapy was defined as therapy for ventricular arrhythmias. Arrhythmias were classified as discrete episodes and storm episodes (≥ 3 episodes within 24 hours). In this trial, no difference was observed in shock efficacy of S-ICD compared with TV-ICD. Although patients in the S-ICD group were more likely to receive an ICD shock, the total number of appropriate shocks was not different between the 2 groups.

Friedman et al (2022) conducted a prospective, single group, nonrandomized, premarket global clinical study involving patients with a class I or IIa indication for an ICD, all of whom received an extravascular ICD system. A total of 356 patients were enrolled, 316 of whom had an implantation attempt. Among the 302 patients in whom ventricular arrhythmia could be induced and who completed the defibrillation testing protocol, the percentage of patients with successful defibrillation was 98.7%; 299 of 316 patients (94.6%) were discharged with a working ICD system. At 6 months, 25 major complications were observed, in 23 of 316 patients (7.3%). The success rate of anti-tachycardia pacing, as assessed with generalized estimating equations, was 50.8% (95% CI, 23.3 to 77.8). A total of 29 patients received 118 inappropriate shocks for 81 arrhythmic episodes. Eight systems were explanted without extravascular ICD replacement over the 10.6-month mean follow-up period. They found that extravascular ICDs were implanted safely and were able to detect and terminate induced ventricular arrhythmias at the time of implantation.

Green et al (2012) conducted a systematic review and meta-analysis to assess the predictive value of late gadolinium enhancement (LGE) cardiac magnetic resonance (CMR) for future cardiac events and death in hypertrophic cardiomyopathy (HCM). Four studies were evaluated that included 1,063 patients over an average follow-up of 3.1 years. The pooled prevalence of LGE was 60%. The pooled odds ratios (OR) demonstrate that LGE by CMR correlated with cardiac death (pooled OR: 2.92, 95% confidence interval [CI]: 1.01 to 8.42; $p=0.047$), heart failure death (pooled OR: 5.68, 95% CI: 1.04 to 31.07; $p=0.045$), and all-cause mortality (pooled OR: 4.46, 95% CI: 1.53 to 13.01; $p=0.006$), and showed a trend toward significance for predicting sudden death/aborted sudden death (pooled OR: 2.39, 95% CI: 0.87 to 6.58; $p=0.091$). Late gadolinium enhancement by CMR has prognostic value in

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predicting adverse cardiovascular events among HCM patients. There are significant relationships between LGE and cardiovascular mortality, heart failure death, and all-cause mortality in HCM. Additionally, LGE and SCD/aborted SCD displayed a trend toward significance.

PROFESSIONAL GUIDELINE(S)

Professional Society Guidelines referenced for this policy:

Professional Society	Title of Guideline	Year
American College of Cardiology (ACC)/ American Heart Association (AHA)/American Society of Echocardiography (ASE)/Heart Failure Society of America (HFSA)/Heart Rhythm Society (HRS)/Society of Cardiovascular Angiography & Interventions (SCAI)/Society of Cardiovascular Computed Tomography (SCCT)/Society of Cardiovascular Magnetic Resonance (SCMR)	Appropriate Use Criteria for Implantable Cardioverter Defibrillators, Cardiac Resynchronization Therapy, and Pacing	2025
ACC/AHA/ACCP/HRS	Guidelines for the Diagnosis and Management of Atrial Fibrillation	2023
AHA/ACC/HFSA	Guideline for the Management of Heart Failure	2022
European Society of Cardiology (ESC)	Guidelines for the management of patients with ventricular arrhythmias and the prevention of sudden cardiac death	2022
ESC	Guidelines for the diagnosis and treatment of acute and chronic heart failure	2021
AHA/ACC	Guideline for the Diagnosis and Treatment of Patients with Hypertrophic Cardiomyopathy	2020
AHA/ACC/HRS	Guideline for management of patients with ventricular arrhythmias and the prevention of	2017

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	sudden cardiac death	
ACC Foundation (ACCF)/AHA/HRS	Focused Update of the 2008 Guidelines for Device-Based Therapy of Cardiac Rhythm Abnormalities	2012

In the 2020 AHA/ACC Guideline for the diagnosis and treatment of Patients with Hypertrophic Cardiomyopathy (HCM) they recommend the following for patients that are at high risk for sudden cardiac death:

- For patients with HCM, and previous documented cardiac arrest or sustained VT, ICD placement is recommended.
- For adults with HCM with one or more major risk factor for SCD, it is reasonable to offer ICD placement. These major risk factors include:
 - Sudden death judged definitively or likely attributable to HCM in one or more first degree or close relatives who are 50 years of age or younger;
 - Massive LVH greater than or equal to 30mm in any LV segment;
 - Greater or equal to one episode(s) of syncope suspected by clinical history to be arrhythmic;
 - LV atypical aneurysm, independent of size;
 - LV systolic dysfunction (Ejection Fraction (EF) less than 50%).
- Recommendations for selection of ICD device type:
 - Either a single chamber transvenous ICD or subcutaneous depending on shared decision making, taking into consideration lifestyle, need for pacing etc.
 - Single coil ICD leads are recommended in preference to dual coil leads.
 - Dual chamber ICDs are reasonable for patients with a need for atrioventricular sequential pacing for bradycardia/conduction abnormalities, or as an attempt to relieve symptoms of obstructive HCM (most commonly in patients greater than 65 years of age).
 - In adult patients with obstructive HCM receiving an ICD who have NYHA class II to ambulatory class IV HF, LBBB, and LVEF less than 50%, cardiac resynchronization therapy for symptom is reasonable.
- Recommendation for CMR imaging:
 - For patients with HCM who are not otherwise identified as high risk for SCD, or in whom a decision to proceed with ICD remains uncertain after clinical assessment. CMR imaging is beneficial to assess for maximum LV wall thickness, EF, LV apical aneurysm, and extent of myocardial fibrosis with LGE.

REGULATORY STATUS

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The United States Food and Drug Administration (FDA) regulates cardiac devices as medical devices. All cardiac devices including related components require FDA approval before marketing and use in the United States to ensure they are safe and effective for human use. Refer to the FDA Medical Device website. Available from: <https://www.fda.gov/medical-devices> [accessed 2025 Dec 23]

The FDA lists the most serious type of medical device recalls as well as early alert communications about corrective actions being taken by companies that the FDA believes are likely to be the most serious type of recalls on our website by the date that the FDA posts the information on our website. Available from: [Medical Device Recalls | FDA](#) [accessed 2025 Dec 23]

Medtronic PLC received FDA approval for their extravascular implantable cardioverter defibrillator (EV ICD) system, which consists of an ICD system with a substernal implantable defibrillator electrode to deliver defibrillation and anti-tachycardia pacing therapy.

The S-ICD system (Cameron Health, Inc.) received U.S. Food and Drug Administration (FDA) approval on September 28, 2012.

CODE(S)

- Codes may not be covered under all circumstances.
- Code list may not be all inclusive (AMA and CMS code updates may occur more frequently than policy updates).
- (E/I)=Experimental/Investigational
- (NMN)=Not medically necessary/appropriate

CPT Codes

Code	Description
33215	Repositioning of previously implanted transvenous pacemaker or implantable defibrillator (right atrial or right ventricular) electrode
33216	Insertion of a single transvenous electrode, permanent pacemaker or implantable defibrillator
33217	Insertion of 2 transvenous electrodes, permanent pacemaker or implantable defibrillator
33218	Repair of single transvenous electrode, permanent pacemaker or implantable defibrillator
33220	Repair of two transvenous electrodes for permanent pacemaker or implantable defibrillator
33223	Relocation of skin pocket for implantable defibrillator
33230	Insertion of implantable defibrillator pulse generator only; with existing dual leads
33231	with existing multiple leads

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Code	Description
33240	with existing single lead
33241	Removal of implantable defibrillator pulse generator only
33243	Removal of single or dual chamber implantable defibrillator electrode(s); by thoracotomy
33244	Removal of single or dual chamber implantable defibrillator electrode(s); by transvenous extraction
33249	Insertion or replacement of permanent implantable defibrillator system, with transvenous lead(s), single or dual chamber
33262	Removal of implantable defibrillator pulse generator with replacement of implantable defibrillator pulse generator; single lead system
33263	dual lead system
33264	multiple lead system
33270	Insertion or replacement of permanent subcutaneous implantable defibrillator system, with subcutaneous electrode, including defibrillation threshold evaluation, induction of arrhythmia, evaluation of sensing for arrhythmia termination, and programming or reprogramming of sensing or therapeutic parameters, when performed
33271	Insertion of subcutaneous implantable defibrillator electrode
33272	Removal of subcutaneous implantable defibrillator electrode
33273	Repositioning of previously implanted subcutaneous implantable defibrillator electrode
93260	Programming device evaluation (in person) 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; implantable subcutaneous lead defibrillator system
93261	Interrogation device evaluation (in person) with analysis, review and report by a physician or other qualified health care professional, includes connection, recording and disconnection per patient encounter; implantable subcutaneous lead defibrillator system
93282	Programming device evaluation (in person) 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; single lead transvenous implantable defibrillator system

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Code	Description
93283	dual lead transvenous implantable defibrillator system
93295	Interrogation device evaluation(s) (remote), up to 90 days; single, dual, or multiple lead implantable defibrillator system with interim analysis, review(s) and report(s) by a physician or other qualified health care professional
93640	Electrophysiologic evaluation of single or dual chamber pacing cardioverter-defibrillator leads including defibrillation threshold evaluation (induction of arrhythmia, evaluation of sensing and pacing for arrhythmia termination) at time of initial implantation or replacement
93641	Electrophysiologic evaluation of single or dual chamber pacing cardioverter-defibrillator leads including defibrillation threshold evaluation (induction of arrhythmia, evaluation of sensing and pacing for arrhythmia termination) at time of initial implantation or replacement; with testing of single or dual chamber pacing cardioverter-defibrillator pulse generator
93642	Electrophysiologic evaluation of single or dual chamber transvenous pacing cardioverter-defibrillator leads (includes defibrillation threshold evaluation, induction of arrhythmia, evaluation of sensing and pacing for arrhythmia termination, and programming or reprogramming of sensing or therapeutic parameters)
93644	Electrophysiologic evaluation of subcutaneous implantable defibrillator (includes defibrillation threshold evaluation, induction of arrhythmia, evaluation of sensing for arrhythmia termination, and programming or reprogramming of sensing or therapeutic parameters)
0571T (E/I)	Insertion or replacement of implantable cardioverter-defibrillator system with substernal electrode(s), including all imaging guidance and electrophysiological evaluation (includes defibrillation threshold evaluation, induction of arrhythmia, evaluation of sensing for arrhythmia termination, and programming or reprogramming of sensing or therapeutic parameters), when performed
0572T (E/I)	Insertion of substernal implantable defibrillator electrode
0573T (E/I)	Removal of substernal implantable defibrillator electrode
0574T (E/I)	Repositioning of previously implanted substernal implantable defibrillator-pacing electrode
0575T (E/I)	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

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Code	Description
0576T (E/I)	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 (E/I)	Electrophysiological 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 (E/I)	Interrogation device evaluation(s) (remote), up to 90 days, substernal lead implantable cardioverter-defibrillator system with interim analysis, review(s) and report(s) by a physician or other qualified health care professional (Report 0578T only once per 90 days)
0579T (E/I)	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 (Report 0579T only once per 90 days)
0580T (E/I)	Removal of substernal implantable defibrillator pulse generator only
0614T (E/I)	Removal and replacement of substernal implantable defibrillator pulse generator

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HCPCS Codes

Code	Description
C1721	Cardioverter-defibrillator, dual chamber (implantable)
C1722	Cardioverter-defibrillator, single chamber (implantable)
C1882	Cardioverter-defibrillator, other than single or dual chamber (implantable)
C1895	Lead, cardioverter-defibrillator, endocardial dual coil (implantable)
C1896	Lead, cardioverter-defibrillator, other than endocardial single or dual coil (implantable)
C1899	Lead, pacemaker / cardioverter-defibrillator, combination (implantable)

ICD10 Codes

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Code	Description
I25.10- I25.119	Atherosclerotic heart disease of native coronary artery (code range)
I25.3-I25.42	Aneurysm of heart (code range)
I25.5-I25.6	Myocardial ischemia (code range)
I25.700- I25.739	Atherosclerosis of coronary artery bypass graft(s), unspecified, with angina pectoris (code range)
I25.750- I25.769	Atherosclerosis of bypass graft of coronary artery of transplanted heart (code range)
I25.790- I25.799	Atherosclerosis of other coronary artery bypass graft(s) (code range)
I25.810	Atherosclerosis of other coronary vessels without angina pectoris
I25.811	Atherosclerosis of native coronary artery of transplanted heart without angina pectoris
I25.812	Atherosclerosis of bypass graft of coronary artery of transplanted heart without angina pectoris
I25.82	Chronic total occlusion of coronary artery
I25.83-I25.84	Coronary atherosclerosis due to lipid rich plaque or calcified coronary lesion (code range)
I25.89	Other forms of chronic ischemic heart disease
I25.9	Chronic ischemic heart disease, unspecified
I42.0-I42.9	Cardiomyopathy (code range)
I46.2-I46.9	Cardiac arrest (code range)
I47.0	Re-entry ventricular arrhythmia
I47.2	Ventricular tachycardia
I48.0-I48.91	Atrial fibrillation and flutter (code range)
I49.01-I49.02	Ventricular fibrillation or ventricular flutter (code range)
I49.9	Cardiac arrhythmia, unspecified

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Code	Description
I50.1	Left ventricular failure, unspecified
I50.20-I50.23	Systolic (congestive) heart failure (code range)
I50.30-I50.33	Diastolic (congestive) heart failure (code range)
I50.40-I50.43	Combined systolic (congestive) and diastolic (congestive) heart failure (code range)
I50.9	Heart failure, unspecified

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SEARCH TERMS

Not Applicable

CENTERS FOR MEDICARE AND MEDICAID SERVICES (CMS)

[Implantable Cardioverter Defibrillators \(ICDs\) \(NCD 20.4\)](#) [accessed 2025 Dec 22]

PRODUCT DISCLAIMER

- Services are contract dependent; if a product does not cover a service, medical policy criteria do not apply.
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POLICY HISTORY/REVISION

Committee Approval Dates

10/18/01, 06/20/02, 04/24/03, 10/15/03, 02/19/04, 03/17/05, 12/15/05, 09/21/06, 07/19/07, 08/21/08, 07/16/09, 07/15/10, 08/18/11, 08/16/12, 08/15/13, 08/21/14, 07/16/15, 03/17/16, 01/19/17, 02/15/18, 02/21/19, 04/16/20, 02/18/21, 08/19/21, 08/18/22, 08/17/23, 04/18/24, 01/23/25, 02/19/26

Date

Summary of Changes

02/19/26

- Off-cycle policy update. Policy criteria updates included post cardiac arrest, structural heart disease with sustained VT, syncope of undetermined origin

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	and positive EP study and unexplained syncope and sustained VT with normal LV function. New primary and secondary prevention sections identified with subheaders.
01/23/25	<ul style="list-style-type: none">• Off-cycle policy update. Policy criteria added for permanent pacemakers.
01/01/25	<ul style="list-style-type: none">• Summary of changes tracking implemented.
10/18/01	<ul style="list-style-type: none">• Original effective date