



Magellan Healthcare	
Clinical guideline IMPLANTABLE CARDIOVERTER DEFIBRILLATOR (ICD)	Original Date: February, 2013 Page 1 of 9
CPT Codes: 33230, 33240, 33249	Last Review Date: March 2017
Guideline Number: NIA_CG_321	Last Revised Date: May 2016
Responsible Department: Clinical Operations	Implementation Date: January 2018

INTRODUCTION

Implantable cardioverter defibrillators (ICDs) are indicated for the treatment of life-threatening ventricular tachycardia and ventricular fibrillation. An ICD system includes a pulse generator and one or more leads. ICDs are indicated both for patients who have survived life threatening rhythm disturbances (secondary prevention) and for those who are at risk for them (primary prevention). Most ICD implantations are for primary prevention in patients with ischemic cardiomyopathy. Studies published in the last decade have confirmed improved survival in patient with reduced left ventricular ejection fraction (LVEF) even when no cardiac arrhythmias have been noted.

Approximately one third of patients who receive ICDs are also candidates for cardiac resynchronization therapy (CRT) because of congestive heart failure (CHF) and an abnormally wide QRS. CRT typically requires three leads, one each to pace the right and left ventricles, and a third to pace the atrium. This allows near-simultaneous stimulation (resynchronization) of both ventricles. CRT improves cardiac function and quality of life and decreases cardiac events and mortality among appropriately chosen patients. The improved survival in patients with CRT is greater than that provided by ICD insertion alone. Criteria for CRT are based on a 2012 focused update of the ACC/AHA/HRS 2008 ICD guideline. This guideline supports approval of ICD and CRT indications that are classed as IIb or higher. Relevant considerations are assigning designations I, IIa, and IIb are LVEF, QRS pattern and duration, and whether atrial fibrillation is present.

Initial Clinical Reviewers (ICRs) and Physician Clinical Reviewers (PCRs) must be able to apply criteria based on individual needs and based on an assessment of the local delivery system.

INDICATIONS FOR ICD INSERTION:

- Cardiac arrest secondary to ventricular fibrillation (VF) or hemodynamically unstable sustained (at least 30 seconds) ventricular tachycardia (VT) after evaluation of etiology of event and exclusion of completely reversible causes.
- Spontaneous sustained VT in patients with structural heart disease, whether hemodynamically stable or unstable.
- Syncope of undetermined origin with hemodynamically significant sustained (30 seconds duration, causing hemodynamic collapse, or requiring cardioversion) VT or VF induced at electrophysiological study.

- LVEF \leq 35% due to prior myocardial infarction (MI), New York Heart Association (NYHA) functional Class II or III and at least 40 days post-MI and 90 days post-revascularization.
- Non-ischemic dilated cardiomyopathy (DCM) with LVEF less than or equal to 35% and NYHA functional Class I, II, or III and at least 90 days after diagnosis of DCM.
- LVEF \leq 30% due to prior MI and at least 40 days post-MI and 90 days post-revascularization.
- Non-sustained VT with prior MI and LVEF less than or equal to 40% and inducible VF or sustained VT at electrophysiological study.
- Unexplained syncope with significant LV dysfunction and nonischemic DCM.
- Sustained VT with normal or near-normal LV function.
- Hypertrophic cardiomyopathy (HCM) who have one or more major risk factors for Sudden Cardiac Death (SCD). Risk factors include syncope, nonsustained VT, family history of sudden death, 30 mm septal thickness, or abnormal blood pressure response to exercise.
- Arrhythmogenic right ventricular dysplasia/cardiomyopathy (ARVD/C) and one or more risk factors for SCD, which include positive EP study, nonsustained VT, male gender, severe right ventricular (RV) dilatation, extensive RV involvement, LV involvement, unexplained syncope, or high-risk genotype.
- Long-QT syndrome with syncope and/or VT despite beta blocker therapy.
- Non-hospitalized patients awaiting cardiac transplantation.
- Brugada syndrome with syncope or documented VT.
- Catecholaminergic polymorphic VT with syncope and/or documented sustained VT while receiving beta blockers.
- Cardiac sarcoidosis or giant cell myocarditis or Chagas disease, accompanied by clinically relevant arrhythmia.
- Long-QT syndrome and risk factors for SCD, including syncope despite drug therapy, family history of sudden cardiac death, concern regarding medication compliance or intolerance, or high-risk genotype.
- Syncope and advanced structural heart disease (including congenital) in which thorough invasive and noninvasive investigations have failed to define a cause.
- Familial cardiomyopathy associated with SCD.
- LV noncompaction.

CONTRAINDICATIONS FOR ICD IMPLANTATION:

- Patients with less than 1 year of expected survival, even if they otherwise meet ICD implantation criteria.
- Incessant VT or VF.
- Significant psychiatric illnesses that may be aggravated by device implantation or that may preclude systematic follow-up.
- NYHA Class IV symptoms with drug-refractory congestive heart failure and who are not eligible for cardiac transplantation, ventricular assist device, or CRT-D.
- Syncope of undetermined origin with no inducible ventricular tachyarrhythmias or structural heart disease.

- VF or VT amenable to surgical or catheter ablation (e.g., atrial arrhythmias associated with the Wolff-Parkinson-White syndrome, RV or LV outflow tract VT, idiopathic VT, or fascicular VT), in the absence of structural heart disease.
- Ventricular tachyarrhythmias due to a completely reversible disorder in the absence of structural heart disease (e.g., electrolyte imbalance, drugs, or trauma).

INDICATIONS FOR CARDIAC RESYNCHRONIZATION THERAPY (CRT):

- LVEF \leq 35% and:
 - sinus rhythm with left bundle-branch block (LBBB) with a QRS duration \geq 120 ms and NYHA class II, III, or ambulatory IV symptoms on Guideline-Directed Medical Therapy (GDMT).
 - sinus rhythm with a non-LBBB pattern with a QRS duration \geq 120 ms and NYHA class III, or ambulatory class IV symptoms on GDMT.
 - sinus rhythm with a non-LBBB pattern with a QRS duration \geq 150 ms and NYHA class II
 - atrial fibrillation if:
 - the patient requires ventricular pacing or otherwise meets CRT criteria *and*
 - AV nodal ablation or pharmacologic rate control will allow near 100% ventricular pacing with CRT.
 - planned new or replacement device placement and anticipated requirement for significant (40%) ventricular pacing.
- LVEF \leq 30% and ischemic heart failure with sinus rhythm and LBBB with a QRS duration \geq 150 ms and NYHA class I symptoms on GDMT.

CONTRAINDICATIONS FOR CARDIAC RESYNCHRONIZATION THERAPY (CRT):

- NYHA class I or II symptoms and non-LBBB pattern with QRS duration less than 150 ms.
- A projected survival of less than 1 year.

ADDITIONAL INFORMATION:

Implantable cardioverter defibrillators (ICDs) are indicated for the treatment of life-threatening ventricular tachycardia and ventricular fibrillation. An ICD system includes a pulse generator and one or more leads. ICDs are indicated both for patients who have survived life threatening rhythm disturbances (secondary prevention) and for those who are at risk for them (primary prevention).

- An ICD continually monitors heart rhythm. If a rapid rhythm is detected, the device delivers electrical therapy directly to the heart muscle in order to terminate the rapid rhythm and restore a normal heart rhythm. There are two types of therapy that can be delivered.
 - Rapid pacing, which is painless, is often effective in terminating ventricular tachycardia.
 - High-voltage shocks, which are painful to the patient, are necessary for ventricular fibrillation and also for instances where rapid pacing has failed to correct ventricular tachycardia.

- In addition, all ICDs have pacing capability, and they deliver pacing therapy for slow heart rhythms (bradycardia).
- The parameters defining limits for pacing therapy and for tachycardia therapy are programmable using noninvasive radio signals on all available ICDs.
- **Waiting Period:** An important issue in the timing of ICD insertion for primary prevention, which has garnered increasing attention recently, is the “waiting period” prior to ICD implantation for certain indications. This has resulted from guidelines and payment policies, predominantly on the part of CMS, which mirror the inclusion criteria of published primary and secondary prevention trials. For example, most primary prevention trials have excluded patients with recent coronary revascularization (under 90 days) or recent myocardial infarction (under 40 days). In addition, studies of patients who have received ICDs early after myocardial infarction have not demonstrated a mortality benefit.
 - A recent study of a large Medicare database, which received a great deal of media attention, concluded that over 20% of ICD insertions in the United States are “inappropriate”, predominantly due to violations of these waiting periods.
 - Most thought leaders and practicing clinicians feel that the waiting periods are largely reasonable and appropriate, but there are certain clinical scenarios in which following them reduces the quality of care and increases patient risk without any benefit. For example, a patient with a longstanding cardiomyopathy, who is a candidate for an ICD, might have a small non-revascularized non-ST-elevation Myocardial Infarction (STEMI). This patient’s LVEF will certainly not improve over the next 40 days, and withholding an ICD makes little sense.
 - This scenario would be rendered even more problematic if the patient required a pacemaker, since waiting 40 days to upgrade a pacemaker to an ICD would subject the patient (and payer) to two procedures instead of one. Therefore, these guidelines will adhere to the current waiting periods but also provide an opportunity to request exemptions where patient benefit is clearly documented.
- **NYHA Class Definitions:**
 - Class I: No limitation of functional activity or only at levels of exertion that would limit normal individuals.
 - Class II: Slight limitation of activity. Dyspnea and fatigue with moderate exercise.
 - Class III: Marked limitation of activity. Dyspnea with minimal activity.
 - Class IV: Severe limitation of activity. Symptoms even at rest.

ABBREVIATIONS

ARVD/C = Arrhythmogenic right ventricular dysplasia/cardiomyopathy
 AV = Atrioventricular
 CHF = congestive heart failure
 CRT = Cardiac resynchronization therapy
 CRT-D = Cardiac resynchronization therapy ICD system
 DCM = Dilated cardiomyopathy
 EKG = Electrocardiogram
 EPS = Electrophysiologic Study
 GDMT = Guideline-Directed Medical Therapy

HCM = Hypertrophic cardiomyopathy
HRS = Heart Rhythm Society
HV = His-ventricle
ICD = Implantable cardioverter-defibrillator
LBBB = left bundle-branch block
LV = Left ventricular/left ventricle
LVEF = Left ventricular ejection fraction
MI = myocardial infarction
MS = milliseconds
NYHA = New York Heart Association
RV = Right ventricular/right ventricle
STEMI = ST-elevation Myocardial Infarction
SND = Sinus node dysfunction
VT = Ventricular tachycardia
VF = Ventricular fibrillation

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