



National Imaging Associates, Inc.	
Clinical guideline IMPLANTABLE CARDIOVERTER DEFIBRILLATOR (ICD)	Original Date: February 2013
CPT Codes: 33230, 33240, 33249	Last Revised Date: August 2019
Guideline Number: NIA_CG_321	Implementation Date: January 2020

INDICATIONS FOR ICD INSERTION

(Al-Khatib 2017, Epstein 2012, Ponikowski 2016, Priori 2015, Russo 2013, Shen 2017, Yancy 2013)

Ischemic Heart Disease (CAD)

(Al-Khatib 2017, Priori 2015, Russo 2013)

- Patients with documented ventricular fibrillation (VF), hemodynamically unstable ventricular tachycardia (VT), or sustained VT, after exclusion of reversible causes
- Syncope of undetermined origin, with one of the following:
 - Inducible VF or sustained VT at electrophysiological study (EPS), or
 - Left ventricular ejection fraction (LVEF) \leq 35%
- LVEF \leq 35% due to ischemic heart disease and NYHA class II or III, despite guideline-directed medical therapy (GDMT), and at least 40 days post myocardial infarction (MI) and 90 days post-revascularization
- LVEF \leq 30% due to ischemic heart disease, NYHA class I, II, or III despite GDMT, and at least 40 days post-MI and 90 days post-revascularization (Al-Khatib 2017, Russo 2013)

Nonischemic cardiomyopathy (NICM)

(Al-Khatib 2017)

- Patients with documented VF, hemodynamically unstable VT, or sustained VT, after exclusion of reversible causes
- Syncope that is presumed to be due to ventricular arrhythmia
- NICM with LVEF \leq 35% and NYHA functional Class II or III, despite at least 3 months of GDMT
- NICM due to a *Lamin A/C* gene mutation, who have \geq 2 risk factors from the following (NSVT, LVEF $<$ 45%, Male sex, nonmissense mutation)

Advanced Heart Failure & Transplantation

(Al-Khatib 2017, Priori 2015)

- In nonhospitalized patients with NYHA class IV who are candidates for cardiac transplantation or left ventricular assist device (LVAD) (Al-Khatib 2017, Priori 2015, Russo 2013)
- In a patient with an LVAD, sustained ventricular arrhythmias (Al-Khatib 2017)
- In NYHA ambulatory class IV, with appropriate indications for CRT (see Background Information section for definition of ambulatory NYHA class IV)

Myocardial Diseases

- **Hypertrophic cardiomyopathy (HCM)** with ≥ 1 major risk factors for SCD (Al-Khatib 2017, Epstein 2012, Gersh 2011, Shen 2017):
 - Prior sudden cardiac arrest (SCA) due to VT or VF
 - Documentation of sustained VT with syncope or hemodynamic compromise
 - Maximum LV wall thickness ≥ 30 mm
 - SCD in 1 or more first degree relatives
 - ≥ 1 episode of unexplained syncope within the preceding 6 months
 - Documented NSVT with an additional SCD risk modifier (age < 30 yr, delayed hyperenhancement on cardiac MRI, LVOT obstruction, or syncope > 5 yr ago) or high-risk feature (LV aneurysm or LVEF $< 50\%$)
 - Abnormal BP response to exercise with an additional SCD risk modifier or high-risk feature (see above)
 - BP rise < 20 mmHg or fall of > 20 mmHg during exercise
- **Cardiac Sarcoidosis** with one of the following (Al-Khatib 2017, Priori 2015, Shen 2017):
 - Cardiac arrest or documented sustained VT
 - LVEF $\leq 35\%$
 - LVEF $> 35\%$ with inducible sustained ventricular arrhythmia at EPS
 - Syncope and/or scar on CMR or positron emission tomography (PET)
 - Requires a permanent pacemaker
- **Neuromuscular Disorders** with one of the following (Al-Khatib 2017):
 - Primary and secondary prevention, with same indications as for NICM (Priori 2016)
 - Emery-Dreifuss or limb-girdle type I-B muscular dystrophy with progressive cardiac involvement
- **Arrhythmogenic right ventricular cardiomyopathy** and ≥ 1 of the following risk factors for SCD: (Al-Khatib 2017, Calkins 2017, Epstein 2012, Corado 2015, Shen 2017)
 - Resuscitated sudden cardiac arrest
 - Sustained VT
 - Right or left ventricular systolic dysfunction with an ejection fraction $\leq 35\%$
 - Syncope with documented or presumed ventricular arrhythmia

Channelopathies

- **Congenital long QT syndrome** with **one** of the following (Al-Khatib 2017, Epstein 2012, Goldenberg 2008, Priori 2015, Schwartz 2012)
 - Sudden cardiac arrest
 - Sustained VT or recurrent syncope when beta blocker is ineffective or not tolerated
 - QTc > 500 ms on a beta blocker (Al-Khatib 2017)
 - Strong family history of SCD
 - High risk genotype (type 2 and type 3)
- **Brugada syndrome and spontaneous type 1 Brugada electrocardiographic pattern** with **one** of the following:

(Al-Khatib 2017, Epstein 2012, Katsumoto 2018, Priori 2015)

- Cardiac arrest
 - Documented sustained ventricular arrhythmia
 - Syncope due to ventricular arrhythmia
- **Catecholaminergic polymorphic VT** with **one** of the following (Al-Khatib 2017, Priori 2013, Epstein 2012, Russo 2013):
 - Sudden cardiac arrest
 - Syncope or sustained VT
 - Inducible VT or VF
- **Early Repolarization or Short QT Syndrome** with **one** of the following (Al-Khatib 2017, Priori 2015):
 - Cardiac arrest
 - Sustained ventricular arrhythmia
- **Idiopathic Polymorphic VT/VF** with **one** of the following (Al-Khatib 2017):
 - Cardiac arrest due to polymorphic VT or VF

Miscellaneous

Adult & Pediatric Congenital (Structural) Heart Disease (ACHD)

(Al-Khatib 2017, Brugada 2013, Hernandez-Madrid 2018, Khairy 2014, Priori 2015, Shen 2017)

- Cardiac arrest due to VF or VT after exclusion of a reversible etiology
- Systemic LVEF \leq 35%, biventricular physiology, and NYHA class II or III on GDMT.
- Tetralogy of Fallot with one of the following (Al-Khatib 2017, Shen 2017):
 - Spontaneous sustained VT
 - Inducible VF or sustained VT
 - \geq 1 risk from the following list:
 - Prior palliative systemic to pulmonary shunts
 - Unexplained syncope
 - Frequent PVCs
 - Atrial tachycardia
 - Left ventricular dysfunction or diastolic dysfunction
 - NSVT
 - QRS duration \geq 180 ms
 - Dilated right ventricle
 - Severe pulmonary regurgitation or stenosis
- Single or systemic right ventricular ejection fraction (RVEF) $<$ 35%, in the presence of an additional risk factor such as:
 - NSVT
 - Unexplained syncope

- NYHA class II or III, despite GDMT (Al-Khatib 2017, Priori 2015)
 - QRS duration \geq 140 ms
 - Severe systemic AV valve regurgitation
- Syncope of unknown origin in the presence of either advanced ventricular dysfunction (EF < 35%) or marked hypertrophy or inducible sustained VT or VF (Al-Khatib 2017, Shen 2017)
 - Syncope and moderate or complex congenital heart disease (CHD), with high clinical suspicion of ventricular arrhythmias
 - Non-hospitalized patients with CHD awaiting heart transplantation
 - Left ventricular non-compaction that meets same indications as NICM, including a familial history of SCD (Biagini 2006, Russo 2018)

EXEMPTIONS:

Indications for ICD with an Appropriate Pacing Modality in Special Situations

(Katsumoto 2014, Russo 2013)*

- ICD criteria met, and elevated troponin is deemed not due to a myocardial infarction (Al-Khatib 2017)
- ICD criteria met, except for myocardial infarction within 40 days or revascularization within 3 months, but a non-elective permanent pacemaker (new or replacement) is required, and recovery of left ventricular function to LVEF > 35% is uncertain or not expected (Russo 2013)**
- ICD criteria met, except NICM or ischemic cardiomyopathy has not had 3 months' time for LVEF to improve on medical therapy, a non-elective permanent pacemaker is required, and recovery of LVEF is uncertain or not expected**
- Patient met primary prevention criteria for an ICD prior to coronary revascularization, and it is unlikely that LVEF will recover to > 35% despite a 90 day wait (Katsumoto 2014)

*** With these ICD indications, CRT would sometimes be the appropriate pacing modality. CRT is highly likely to be the appropriate modality when > 40% rhythm requires pacing.**

**** These indications avoid a second implantation procedure within less than 3 months.**

BACKGROUND:

(Al-Khatib 2017, Epstein 2012, Ponikowski 2016, Priori 2015, Russo 2013, Shen 2017, Yancy 2013)

The implantable cardioverter defibrillator (ICD) has become valuable in the management of patients with ventricular arrhythmias (VA) capable of causing syncope, cardiac arrest, and sudden cardiac death (SCD).

Patient eligibility for an ICD presumes all of the following:

- Anticipated reasonable quality of life for \geq 1 year post implantation (Katsumoto 2018)
- Patient's ability to live with a shock-delivering device that requires management

- Absence of a *completely* reversible cause that led to VA for which an ICD is being considered (see Background Information section on reversible causes)
- Completion of ≥ 3 months of guideline directed medical therapy (GDMT) for heart failure (HF), unless an intervening indication for pacemaker implantation arises (see Background Information section for definition of GDMT)
- ICD indications are present in the vast majority of scenarios in which cardiac resynchronization therapy (CRT) is appropriate
- Sustained VT is defined as having duration > 30 seconds or requiring termination due to hemodynamic compromise in < 30 seconds

Guidelines for the pediatric population are extrapolated from the adult population, due to a lack of relevant trials (Brugada 2013, Priori 2015)

OVERVIEW:

General

(Al-Khatib 2017, Epstein 2012, Ponikowski 2016, Priori 2015, Russo 2013, Shen 2017, Yancy 2013)

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 OR
 - High-voltage shocks are necessary for ventricular fibrillation and also for instances where rapid pacing has failed to correct the abnormal rhythm
- 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 is an important issue in ICD insertion for primary prevention. This has resulted from guidelines and payment policies which mirror the inclusion criteria of primary and secondary prevention trials (Dukkipati 2017a, Dukkipati 2017b).

NYHA Class Definitions

(Campeau 1976, Goldman 1981, Russo 2013)

- **Class I:** No limitation of functional activity or only at levels of exertion that would limit normal individuals (patient can carry 24 pounds up 8 stairs, play basketball, and shovel soil).

- **Class II:** Slight limitation of activity. Fatigue, palpitation, or dyspnea with moderate exercise (patient able to dance, garden, and walk 4 MPH on level ground).
- **Class III:** Marked limitation of activity. Fatigue, palpitation, or dyspnea with minimal activity (patient able to shower, make bed, bowl or golf, dress, and walk 2.5 MPH on level ground).
- **Class IV:** Severe limitation of activity. Symptoms even at rest, worse with activity (patient unable to comfortably perform any significant activity).
- **Ambulatory Class IV:** Class IV heart failure with: 1) no active acute coronary syndrome; 2) no inotropes; and 3) on GDMT.

Guideline Directed (or Optimal) Medical Therapy for Heart Failure

(Yancy 2013, Yancy 2017)

- Angiotensin converting enzyme (ACE-I), angiotensin receptor blockers (ARB), or combined angiotensin receptor inhibitor and neprilysin inhibitor (ARNI)
- Beta blocker (might be less critical in permanent atrial fibrillation, still recommended) (Kotecha 2017)
- Addition of loop diuretic for all NYHA class II – IV patients
- Addition of hydralazine and nitrate for persistently symptomatic African Americans
- Addition of an aldosterone antagonist, provided eGFR is > 30 ml/mi
- Normal serum sodium and potassium
- Not required for consideration of ICD: Ivabradine for NYHA class II – III, when a beta blocker has failed to reduce a sinus rate to < 70 bpm. Ivabradine listed as a class IIa recommendation, while others are class I recommendations. CRT trials antedated routine use of Ivabradine.

Abbreviations

ACE-I	Angiotensin converting enzyme inhibitor
ACHD	Adult congenital heart disease
ARNI	Combined angiotensin receptor inhibitor and neprilysin inhibitor
ARVD/C	Arrhythmogenic right ventricular dysplasia/cardiomyopathy
AV	Atrioventricular
CAD	Coronary artery disease, same as ischemic heart disease
CHD	Congenital heart disease
CHF	Congestive heart failure
CRT	Cardiac resynchronization therapy
CRT-D	Cardiac resynchronization therapy ICD system
DCM	Dilated cardiomyopathy
ECG	Electrocardiogram
EPS	Electrophysiologic Study
GDMT	Guideline-Directed Medical Therapy
HCM	Hypertrophic cardiomyopathy
HF	Heart failure
HRS	Heart Rhythm Society
HV	His-ventricle
ICD	Implantable cardioverter-defibrillator
LBBB	Left bundle-branch block
LV	Left ventricular/left ventricle
LVAD	Left ventricular assist device, mechanical heart
LVEF	Left ventricular ejection fraction
MI	Myocardial infarction
ms	Milliseconds
NICM	Nonischemic cardiomyopathy
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

POLICY HISTORY:**Review Date:** August 14, 2019**Review Summary:**

- Removed indications under ischemic heart disease for NSVT due to prior MI, LVEF \leq 40%, and inducible VT or VF at EPS
- Removed indications under ischemic heart disease for VT or VF < 48 hours post MI or elective coronary revascularization
- Under NICM, removed indication for peripartum cardiomyopathy with LVEF \leq 35% that persists > 3 months
- Under advanced heart failure and transplantation, removed indication for severe allograft vasculopathy
- Revision to cardiac sarcoidosis indication to add cardiac arrest
- Under hypertrophic cardiomyopathy revised indications for documented NSVT to include an additional SCD risk modifier (age < 30 yr, delayed hyperenhancement on cardiac MRI, LVOT obstruction, or syncope > 5 yr ago) or high risk feature (LV aneurysm or LVEF < 50%)
- Removed indications for giant cell myocarditis and chronic Chagas cardiomyopathy
- Removed indication for hypertensive heart disease with LVH and LVEF \leq 35%
- Under Tetralogy of Fallot added the following indications :
 - Prior palliative systemic to pulmonary shunts
 - Unexplained syncope
 - Frequent PVCs
 - Atrial tachycardia
 - Left ventricular diastolic dysfunction
 - Dilated right ventricle

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Reviewed / Approved by  Patrick Browning, VP, Medical Director

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