



MASSACHUSETTS

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Medical Policy

Implantable Cardioverter Defibrillator

Table of Contents

- [Policy: Commercial](#)
- [Policy: Medicare](#)
- [Authorization Information](#)
- [Coding Information](#)
- [Description](#)
- [Policy History](#)
- [Information Pertaining to All Policies](#)
- [References](#)

Policy Number: 070

BCBSA Reference Number: 7.01.44

NCD/LCD: National Coverage Determination (NCD) for Implantable Automatic Defibrillators (20.4)

Related Policies

- Biventricular Pacemakers (Cardiac Resynchronization Therapy) for the Treatment of Heart Failure, [#101](#)
- Wearable Cardioverter Defibrillators, [#042](#)

Policy

Commercial Members: Managed Care (HMO and POS), PPO, and Indemnity

Adults

The use of the automatic implantable cardioverter defibrillator (ICD) may be considered **[MEDICALLY NECESSARY](#)** in adults who meet the following criteria:

Primary Prevention

- Ischemic cardiomyopathy with New York Heart Association (NYHA) functional Class II or Class III symptoms, a history of myocardial infarction at least 40 days before ICD treatment and left-ventricular ejection fraction of 35% or less; or
- Ischemic cardiomyopathy (IDCM) with NYHA functional Class I symptoms, a history of myocardial infarction at least 40 days before ICD treatment, and left ventricular ejection fraction of 30% or less; or
- Non-ischemic dilated cardiomyopathy (NIDCM) and left ventricular ejection fraction of 35% or less, after reversible causes have been excluded, and the response to optimal medical therapy has been adequately determined; or
- Hypertrophic cardiomyopathy (HCM) with 1 or more major risk factors for sudden cardiac death (history of premature HCM-related sudden death in 1 or more first-degree relatives younger than 50 years; left ventricular hypertrophy greater than 30 mm; 1 or more runs of non-sustained ventricular tachycardia at heart rates of 120 beats per minute or greater on 24-hour Holter monitoring; prior

unexplained syncope inconsistent with neurocardiogenic origin) and judged to be at high risk for sudden cardiac death by a physician experienced in the care of patients with HCM.

- Diagnosis of any one of the following cardiac ion channelopathies and considered to be at high risk for sudden cardiac death:
 - congenital long QT syndrome; OR
 - Brugada syndrome; OR
 - short QT syndrome; OR
 - catecholaminergic polymorphic ventricular tachycardia.

Secondary Prevention

- Patients with a history of a life-threatening clinical event associated with ventricular arrhythmic events such as sustained ventricular tachyarrhythmia, after reversible causes (eg, acute ischemia) have been excluded.

The use of the ICD is considered **INVESTIGATIONAL** for primary prevention patients who meet the following:

- Have had an acute myocardial infarction (i.e., less than 40 days before ICD treatment); or
- Have NYHA Class IV congestive heart failure (unless patient is eligible to receive a combination cardiac resynchronization therapy ICD device); or
- Have had cardiac revascularization procedure in past 3 months (coronary artery bypass graft [CABG] or percutaneous transluminal coronary angioplasty [PTCA]) or are candidates for a cardiac revascularization procedure; or
- Have non-cardiac disease that would be associated with life expectancy less than 1 year.

The use of the ICD for secondary prevention is considered **INVESTIGATIONAL** for patients who do not meet the criteria for secondary prevention.

Pediatrics

The use of the ICD may be considered **MEDICALLY NECESSARY** in children who meet any of the following criteria:

- Survivors of cardiac arrest, after reversible causes have been excluded; or
- Symptomatic, sustained ventricular tachycardia in association with congenital heart disease in patients who have undergone hemodynamic and electrophysiologic evaluation, or
- Congenital heart disease with recurrent syncope of undetermined origin in the presence of either ventricular dysfunction or inducible ventricular arrhythmias.
- Hypertrophic cardiomyopathy (HCM) with 1 or more major risk factors for sudden cardiac death (history of premature HCM-related sudden death in 1 or more first-degree relatives younger than 50 years; massive left ventricular hypertrophy based on age-specific norms; prior unexplained syncope inconsistent with neurocardiogenic origin) and judged to be at high risk for sudden cardiac death by a physician experienced in the care of patients with HCM.
- Diagnosis of any one of the following cardiac ion channelopathies and considered to be at high risk for sudden cardiac death:
 - congenital long QT syndrome; OR
 - Brugada syndrome; OR
 - short QT syndrome; OR
 - catecholaminergic polymorphic ventricular tachycardia.

The use of the ICD is considered **INVESTIGATIONAL** for all other indications in pediatric patients.

Subcutaneous ICD

The use of a subcutaneous ICD may be considered **MEDICALLY NECESSARY** for adults or children who have an indication for ICD implantation for primary or secondary prevention for any of the above reasons and meet all of the following criteria:

- Have a contraindication to a transvenous ICD due to one or more of the following: (1) lack of adequate vascular access; (2) compelling reason to preserve existing vascular access (ie, need for chronic dialysis; younger patient with anticipated long-term need for ICD therapy); or (3) history of need for explantation of a transvenous ICD due to a complication, with ongoing need for ICD therapy.
- Have no indication for antibradycardia pacing; AND
- Do not have ventricular arrhythmias that are known or anticipated to respond to antitachycardia pacing.

The use of a subcutaneous ICD is considered **INVESTIGATIONAL** for individuals who do not meet the criteria outlined above.

Criteria for ICD Implantation in Patients with Cardiac Ion Channelopathies

Individuals with cardiac ion channelopathies may have a history of a life-threatening clinical event associated with ventricular arrhythmic events such as sustained ventricular tachyarrhythmia, after reversible causes, in which case they should be considered for ICD implantation for *secondary* prevention, even if they do not meet criteria for primary prevention.

Indications for consideration for ICD implantation for each cardiac ion channelopathy are as follows:

- Long QT syndrome (LQTS):
 - Patients with a diagnosis of LQTS who are survivors of cardiac arrest.
 - Patients with a diagnosis of LQTS who experience recurrent syncopal events while on betablocker therapy.
- Brugada syndrome (BrS):
 - Patients with a diagnosis of BrS who are survivors of cardiac arrest.
 - Patients with a diagnosis of BrS who have documented spontaneous sustained ventricular tachycardia (VT) with or without syncope.
 - Patients with a spontaneous diagnostic type 1 ECG who have a history of syncope, seizure, or nocturnal agonal respiration judged to be likely caused by ventricular arrhythmias (after noncardiac causes have been ruled out).
 - Patients with a diagnosis of BrS who develop ventricular fibrillation (VF) during programmed electrical stimulation.
- Catecholaminergic polymorphic ventricular tachycardia (CPVT):
 - Patients with a diagnosis of CPVT who are survivors of cardiac arrest.
 - Patients with a diagnosis of CPVT who experience recurrent syncope or polymorphic/bidirectional ventricular tachycardia (VT) despite optimal medical management, and/or left cardiac sympathetic denervation.
- Short QT syndrome (SQTS):
 - Patients with a diagnosis of SQTS who are survivors of cardiac arrest.
 - Patients with a diagnosis of SQTS who are symptomatic and have documented spontaneous VT with or without syncope.
 - Patients with a diagnosis of SQTS or are asymptomatic or symptomatic and have a family history of sudden cardiac death.

Medicare HMO BlueSM and Medicare PPO BlueSM Members

Medical necessity criteria and coding guidance can be found through the link below.

[National Coverage Determination \(NCD\) for Implantable Automatic Defibrillators \(20.4\)](#)

Prior Authorization Information

Inpatient

- For services described in this policy, precertification/preauthorization **IS REQUIRED** for all products if the procedure is performed **inpatient**.

Outpatient

- For services described in this policy, see below for products where prior authorization **might be required** if the procedure is performed **outpatient**.

	Outpatient
Commercial Managed Care (HMO and POS)	Prior authorization is not required .
Commercial PPO and Indemnity	Prior authorization is not required .
Medicare HMO Blue SM	Prior authorization is not required .
Medicare PPO Blue SM	Prior authorization is not required .

CPT Codes / HCPCS Codes / ICD Codes

Inclusion or exclusion of a code does not constitute or imply member coverage or provider reimbursement. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage as it applies to an individual member.

Providers should report all services using the most up-to-date industry-standard procedure, revenue, and diagnosis codes, including modifiers where applicable.

The following codes are included below for informational purposes only; this is not an all-inclusive list.

The above medical necessity criteria MUST be met for the following codes to be covered for Commercial Members: Managed Care (HMO and POS), PPO and Indemnity:

CPT Codes

CPT codes:	Code Description
33216	Insertion of transvenous electrode; single chamber (one electrode) permanent pacemaker or single chamber pacing cardioverter-defibrillator
33217	Dual chamber (two electrodes) permanent pacemaker or dual chamber pacing cardioverter-defibrillator
33240	Insertion of pacing cardioverter-defibrillator pulse generator only; with existing single lead
33218	Repair of single transvenous electrode, permanent pacemaker or pacing cardioverter-defibrillator
33220	Repair of 2 transvenous electrodes for permanent pacemaker or pacing cardioverter-defibrillator
33223	Relocation of skin pocket for cardioverter-defibrillator
33240	Insertion of pacing cardioverter-defibrillator pulse generator only; with existing single lead
33230	Insertion of pacing cardioverter defibrillator pulse generator only; with existing dual leads
33231	Insertion of pacing cardioverter-defibrillator pulse generator only; with existing multiple leads
33241	Removal of pacing cardioverter-defibrillator pulse generator only

33262	Removal of pacing cardioverter-defibrillator pulse generator with replacement of pacing cardioverter-defibrillator pulse generator; single lead system
33263	Removal of pacing cardioverter-defibrillator pulse generator with replacement of pacing cardioverter-defibrillator pulse generator; dual lead system
33264	Removal of pacing cardioverter-defibrillator pulse generator with replacement of pacing cardioverter-defibrillator pulse generator; multiple lead system
33243	Removal of single or dual chamber pacing cardioverter-defibrillator electrode(s); by thoracotomy
33244	Removal of single or dual chamber pacing cardioverter-defibrillator electrode(s); by transvenous extraction
33249	Insertion or replacement of permanent pacing cardioverter-defibrillator system with transvenous lead(s), single or dual chamber
33262	Removal of pacing cardioverter-defibrillator pulse generator with replacement of pacing cardioverter-defibrillator pulse generator; single lead system
33263	Removal of pacing cardioverter-defibrillator pulse generator with replacement of pacing cardioverter-defibrillator pulse generator; dual lead system
33264	Removal of pacing cardioverter-defibrillator pulse generator with replacement of pacing cardioverter-defibrillator pulse generator; 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
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
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)

HCPCS Codes

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)

The following ICD Diagnosis Codes are considered medically necessary when submitted with the CPT and/or HCPCS codes above if medical necessity criteria are met:

ICD-10-CM Diagnosis Codes

ICD-10-CM diagnosis codes:	Code Description
I25.5	Ischemic cardiomyopathy
I25.6	Silent myocardial ischemia
I25.89	Other forms of chronic ischemic heart disease
I25.9	Chronic ischemic heart disease, unspecified
I42.1	Obstructive hypertrophic cardiomyopathy
I42.2	Other hypertrophic cardiomyopathy
I42.0	Dilated cardiomyopathy
I42.5	Other restrictive cardiomyopathy
I45.81	Long QT syndrome
I45.89	Other specified conduction disorders
I47.0	Re-entry ventricular arrhythmia
I47.2	Ventricular tachycardia
I49.01	Ventricular fibrillation
I49.8	Other specified cardiac arrhythmias
I49.9	Cardiac arrhythmia, unspecified
Q24.8	Other specified congenital malformations of heart
T82.110A	Breakdown (mechanical) of cardiac electrode, initial encounter
T82.111A	Breakdown (mechanical) of cardiac pulse generator (battery), initial encounter
T82.118A	Breakdown (mechanical) of other cardiac electronic device, initial encounter
T82.119A	Breakdown (mechanical) of unspecified cardiac electronic device, initial encounter
T82.121A	Displacement of cardiac pulse generator (battery), initial encounter
T82.128A	Displacement of other cardiac electronic device, initial encounter
T82.129A	Displacement of unspecified cardiac electronic device, initial encounter
T82.190A	Other mechanical complication of cardiac electrode, initial encounter
T82.191A	Other mechanical complication of cardiac pulse generator (battery), initial encounter
T82.198A	Other mechanical complication of other cardiac electronic device, initial encounter
T82.199A	Other mechanical complication of unspecified cardiac device, initial encounter
T82.110D	Breakdown (mechanical) of cardiac electrode, subsequent encounter
T82.110S	Breakdown (mechanical) of cardiac electrode, sequela
T82.111D	Breakdown (mechanical) of cardiac pulse generator (battery), subsequent encounter
T82.111S	Breakdown (mechanical) of cardiac pulse generator (battery), sequela
T82.118D	Breakdown (mechanical) of other cardiac electronic device, subsequent encounter
T82.118S	Breakdown (mechanical) of other cardiac electronic device, sequela
T82.120D	Displacement of cardiac electrode, subsequent encounter
T82.120S	Displacement of cardiac electrode, sequela
T82.121D	Displacement of cardiac pulse generator (battery), subsequent encounter
T82.121S	Displacement of cardiac pulse generator (battery), sequela
T82.128D	Displacement of other cardiac electronic device, subsequent encounter
T82.128S	Displacement of other cardiac electronic device, sequela
T82.129D	Displacement of unspecified cardiac electronic device, subsequent encounter
T82.129S	Displacement of unspecified cardiac electronic device, sequela
T82.190D	Other mechanical complication of cardiac electrode, subsequent encounter
T82.190S	Other mechanical complication of cardiac electrode, sequela

T82.191D	Other mechanical complication of cardiac pulse generator (battery), subsequent encounter
T82.191S	Other mechanical complication of cardiac pulse generator (battery), sequela
T82.198D	Other mechanical complication of other cardiac electronic device, subsequent encounter
T82.198S	Other mechanical complication of other cardiac electronic device, sequela
T82.199D	Other mechanical complication of unspecified cardiac device, subsequent encounter
T82.199S	Other mechanical complication of unspecified cardiac device, sequela

Description

VENTRICULAR ARRHYTHMIA AND SUDDEN CARDIAC DEATH

The risk of ventricular arrhythmia and sudden cardiac death (SCD) may be significantly increased in various cardiac conditions such as individuals with ischemic cardiomyopathy, particularly when associated with reduced left ventricular ejection fraction (LVEF) and prior myocardial infarction; nonischemic dilated cardiomyopathy with reduced LVEF; hypertrophic cardiomyopathy and additional risk factors; congenital heart disease, particularly with recurrent syncope; and cardiac ion channelopathies.

Treatment

Implantable cardioverter defibrillators (ICDs) monitor a patient'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 SCD. Indications for ICD placement can be broadly subdivided into (1) secondary prevention, ie, use in patients who have experienced a potentially life-threatening episode of VT (near SCD); and (2) primary prevention, ie, use in patients who are considered at high risk for SCD but who have not yet experienced life-threatening VT or VF.

The standard ICD placement surgery involves placement of a generator in the subcutaneous tissue of the chest wall. Transvenous leads are attached to the generator and threaded intravenously into the endocardium. The leads sense and transmit information on cardiac rhythm to the generator, which analyzes the rhythm information and produces an electrical shock when a malignant arrhythmia is recognized.

A subcutaneous implantable cardioverter defibrillator (S-ICD) has been developed. It does not use transvenous leads and thus avoids the need for venous access and complications associated with the insertion of venous leads. Rather, the 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.

Several automatic ICDs have been approved by the U.S. Food and Drug Administration (FDA) through the premarket approval process. FDA-labeled indications generally include patients who have experienced life-threatening VT associated with cardiac arrest or VT associated with hemodynamic compromise and resistance to pharmacologic treatment. In addition, devices typically have approval in the secondary prevention setting for patients with a previous myocardial infarction and reduced ejection fraction.

Summary

Transvenous ICDs

For individuals who have a high risk of SCD due to ischemic or to nonischemic cardiomyopathy in adulthood who receive TV-ICD placement for primary prevention, the evidence includes multiple well-designed and well-conducted RCTs as well as systematic reviews of these trials. Relevant outcomes are overall survival, morbid events, quality of life, and treatment-related mortality and morbidity. Multiple, well-done RCTs have shown a benefit in overall mortality for patients with ischemic cardiomyopathy and

reduced ejection fraction. RCTs assessing early ICD use following recent myocardial infarction did not support a benefit for immediate vs delayed implantation for at least 40 days. For nonischemic cardiomyopathy, there is less clinical trial data, but pooled estimates of available evidence from RCTs enrolling patients with nonischemic cardiomyopathy and from subgroup analyses of RCTs with mixed populations have supported a survival benefit for this group. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

For individuals who have a high risk of SCD due to HCM in adulthood who receive TV-ICD placement for primary prevention, the evidence includes several large registry studies. Relevant outcomes are overall survival, morbid events, quality of life, and treatment-related mortality and morbidity. In these studies, the annual rate of appropriate ICD discharge ranged from 3.6% to 5.3%. Given the long-term high risk of SCD in patients with HCM, with the assumption that appropriate shocks are life-saving, these rates are considered adequate evidence to support the use of ICDs in patients with HCM. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

For individuals who have a high risk of SCD due to an inherited cardiac ion channelopathy who receive TV-ICD placement for primary prevention, the evidence includes small cohort studies of patients with these conditions treated with ICDs. Relevant outcomes are overall survival, morbid events, quality of life, and treatment-related mortality and morbidity. The limited evidence for patients with long QT syndrome, catecholaminergic polymorphic ventricular tachycardia, and Brugada syndrome has reported high rates of appropriate shocks. No studies were identified on the use of ICDs for patients with short QT syndrome.

Studies comparing outcomes between patients treated and untreated with ICDs are not available. However, given the relatively small patient populations with these channelopathies and the high risk of cardiac arrhythmias, clinical trials are unlikely. Given the long-term high risk of SCD in patients with inherited cardiac ion channelopathy, with the assumption that appropriate shocks are life-saving, these rates are considered adequate evidence to support the use of TV-ICDs in patients with inherited cardiac ion channelopathy. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

For individuals who have had symptomatic life-threatening sustained VT or VF or who have been resuscitated from sudden cardiac arrest (secondary prevention) who receive TV-ICD placement, the evidence includes multiple well-designed and well-conducted RCTs as well as systematic reviews of these trials. Relevant outcomes are overall survival, morbid events, quality of life, and treatment-related mortality and morbidity. Systematic reviews of RCTs have demonstrated a 25% reduction in mortality for ICD compared with medical therapy. Analysis of data from a large administrative database has confirmed that this mortality benefit is generalizable to the clinical setting. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

Subcutaneous ICDs

For individuals who need an ICD and have a contraindication to a TV-ICD but no indications for antibradycardia pacing and no antitachycardia pacing-responsive arrhythmias who receive S-ICD placement, the evidence includes nonrandomized studies and case series. Relevant outcomes are overall survival, morbid events, quality of life, and treatment-related mortality and morbidity. Nonrandomized controlled studies have reported success rates in terminating laboratory-induced VF that are similar to TV-ICD. Case series have reported high rates of detection and successful conversion of VF, and inappropriate shock rates in the range reported for TV-ICD. Given the need for ICD placement in this population at risk for SCD, with the assumption that appropriate shocks are life-saving, these rates are considered adequate evidence to support the use of S-ICDs in patients with contraindication to TV-ICD. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

For individuals who have need for an ICD and have no contraindication to TV-ICD but no indications for antibradycardia pacing and no antitachycardia pacing-responsive arrhythmias who receive S-ICD placement, the evidence includes nonrandomized studies and case series. Relevant outcomes are overall survival, morbid events, quality of life, and treatment-related mortality and morbidity. Nonrandomized controlled studies have reported success rates in terminating laboratory-induced VF that are similar to TV-ICD. However, there is scant evidence on comparative clinical outcomes of both types of ICD over longer periods. Case series have reported high rates of detection and successful conversion of ventricular tachycardia, and inappropriate shock rates in the range reported for TV-ICD. This evidence does not support conclusions on whether there are small differences in efficacy between the 2 types of devices, which may be clinically important due to the nature to the disorder being treated. Also, adverse event rates are uncertain, with variable rates reported. At least 1 RCT is currently underway comparing S-ICD with TV-ICD. The evidence is insufficient to determine the effects of the technology on health outcomes.

Policy History

Date	Action
6/2018	New references added from BCBSA National medical policy. Background and summary clarified.
1/2018	Clarified coding information.
7/2017	New references added from BCBSA National medical policy.
7/2016	New references added from BCBSA National medical policy.
4/2016	BCBSA National medical policy review. Policy statement added that the ICD is considered investigational for secondary prevention patients who do not meet medical necessity criteria for secondary prevention. Effective 4/1/2016.
3/2016	BCBSA National medical policy review. ICD medically necessary for patients with cardiac ion channelopathies with conditions; S-ICD medically necessary in limited situations. Effective 3/1/2016.
1/2015	Clarified coding information.
6/2014	Updated Coding section with ICD10 procedure and diagnosis codes, effective 10/2015.
5/2014	BCBSA National medical policy review. Policy statement on secondary prevention in adults clarified. Effective 5/1/2014.
1/2014	Coverage added for subcutaneous implantable cardiac defibrillators for Medicare Advantage based on NCD 20.4. Effective immediately 1/7/2014.
4/2013	BCBSA National medical policy review. New investigational indications described. Effective 4/1/2013.
11/2011-4/2012	Medical policy ICD 10 remediation: Formatting, editing and coding updates. No changes to policy statements.
1/1/2012	Reviewed 4/2011 Medical Policy Group – Cardiology and Pulmonology. No changes to policy statements.
4/2010	Reviewed - Medical Policy Group - Cardiology and Pulmonology. No changes to policy statements.
3/2010	BCBS Association National Policy Review No changes to policy statements.
4/2009	Reviewed - Medical Policy Group - Cardiology and Pulmonology. No changes to policy statements.
2/2009	BCBS Association National Policy Review No changes to policy statements.
12/2008	New policy describing covered and non-covered indications. Effective 12/2008.

Information Pertaining to All Blue Cross Blue Shield Medical Policies

Click on any of the following terms to access the relevant information:

[Medical Policy Terms of Use](#)

[Managed Care Guidelines](#)

[Indemnity/PPO Guidelines](#)

[Clinical Exception Process](#)

[Medical Technology Assessment Guidelines](#)

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