Medical Policy
Implantable Cardioverter Defibrillator

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Policy Number: 070
BCBSA Reference Number: 7.01.44

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.

- Diagnosis of cardiac sarcoidosis and considered to be at high risk for sudden cardiac death.

**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.

Criteria for ICD placement in patients with cardiac ion channelopathies derive from results of clinical input, a 2013 consensus statement from the HRS, European Heart Rhythm Association (EHRA), and the Asia-Pacific Heart Rhythm Society on the diagnosis and management of patients with inherited primary arrhythmia syndromes (Priori et al [2013]), 2017 guidelines from ACC, AHA, and HRS on the management of heart failure (Al-Khatib et al [2017]), and a report from the HRS and EHRA's Second Consensus Conference on Brugada syndrome.

Indications for consideration for ICD placement 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 β-blocker 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 electrocardiogram (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 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 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 asymptomatic 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.

**Criteria for Implantable Cardioverter Defibrillator Implantation in Patients with Cardiac Sarcoid**
Criteria for ICD placement in patients with cardiac sarcoid derive from a 2014 consensus statement from the Heart Rhythm Society (HRS) and 2017 joint guidelines from the American Heart Association, American College of Cardiology, and HRS.

Indications for consideration of ICD placement in patients diagnosed with cardiac sarcoid are as follows:

- Spontaneous sustained ventricular arrhythmias, including prior cardiac arrest, if meaningful survival of greater than 1 year is expected;
• LVEF 35% or less, despite optimal medical therapy and a period of immunosuppression (if there is active inflammation), if meaningful survival of greater than 1 year is expected;
• LVEF greater than 35%, if meaningful survival of greater than 1 year is expected; AND
  o syncope or near-syncope, felt to be arrhythmic in etiology OR
  o evidence of myocardial scar by cardiac MRI or positron emission tomographic (PET) scan OR
  o Inducible sustained ventricular arrhythmias (>30 seconds of monomorphic VT or polymorphic VT) or clinically relevant VF
• An indication for permanent pacemaker implantation.

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.

<table>
<thead>
<tr>
<th>Commercial Managed Care (HMO and POS)</th>
<th>Prior authorization is not required.</th>
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</thead>
<tbody>
<tr>
<td>Commercial PPO and Indemnity</td>
<td>Prior authorization is not required.</td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>CPT codes:</th>
<th>Code Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>33216</td>
<td>Insertion of transvenous electrode; single chamber (one electrode) permanent pacemaker or single chamber pacing cardioverter-defibrillator</td>
</tr>
<tr>
<td>33217</td>
<td>Dual chamber (two electrodes) permanent pacemaker or dual chamber pacing cardioverter-defibrillator</td>
</tr>
<tr>
<td>33249</td>
<td>Insertion or replacement of permanent pacing cardioverter-defibrillator system with transvenous lead(s), single or dual chamber</td>
</tr>
<tr>
<td>33270</td>
<td>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</td>
</tr>
<tr>
<td>33271</td>
<td>Insertion of subcutaneous implantable defibrillator electrode</td>
</tr>
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</table>

HCPCS Codes

<table>
<thead>
<tr>
<th>HCPCS codes:</th>
<th>Code Description</th>
</tr>
</thead>
</table>

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

<table>
<thead>
<tr>
<th>ICD-10-CM diagnosis codes:</th>
<th>Code Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>D86.85</td>
<td>Sarcoid myocarditis</td>
</tr>
<tr>
<td>D86.89</td>
<td>Sarcoidosis of other sites</td>
</tr>
<tr>
<td>I25.5</td>
<td>Ischemic cardiomyopathy</td>
</tr>
<tr>
<td>I25.6</td>
<td>Silent myocardial ischemia</td>
</tr>
<tr>
<td>I25.89</td>
<td>Other forms of chronic ischemic heart disease</td>
</tr>
<tr>
<td>I25.9</td>
<td>Chronic ischemic heart disease, unspecified</td>
</tr>
<tr>
<td>I42.1</td>
<td>Obstructive hypertrophic cardiomyopathy</td>
</tr>
<tr>
<td>I42.2</td>
<td>Other hypertrophic cardiomyopathy</td>
</tr>
<tr>
<td>I42.0</td>
<td>Dilated cardiomyopathy</td>
</tr>
<tr>
<td>I42.5</td>
<td>Other restrictive cardiomyopathy</td>
</tr>
<tr>
<td>I45.81</td>
<td>Long QT syndrome</td>
</tr>
<tr>
<td>I45.89</td>
<td>Other specified conduction disorders</td>
</tr>
<tr>
<td>I46.2</td>
<td>Cardiac arrest due to underlying cardiac condition</td>
</tr>
<tr>
<td>I46.8</td>
<td>Cardiac arrest due to other underlying condition</td>
</tr>
<tr>
<td>I46.9</td>
<td>Cardiac arrest, cause unspecified</td>
</tr>
<tr>
<td>I47.0</td>
<td>Re-entry ventricular arrhythmia</td>
</tr>
<tr>
<td>I47.2</td>
<td>Ventricular tachycardia</td>
</tr>
<tr>
<td>I49.01</td>
<td>Ventricular fibrillation</td>
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<tr>
<td>I49.8</td>
<td>Other specified cardiac arrhythmias</td>
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<td>I49.9</td>
<td>Cardiac arrhythmia, unspecified</td>
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<tr>
<td>Q24.8</td>
<td>Other specified congenital malformations of heart</td>
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<tr>
<td>Z86.74</td>
<td>Personal history of sudden cardiac arrest</td>
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### 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 ischemic cardiomyopathy, particularly when associated with reduced left ventricular ejection fraction and prior myocardial infarction; nonischemic dilated cardiomyopathy with reduced left ventricular ejection fraction; 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 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 ventricular fibrillation.

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 ventricular fibrillation shock when a malignant arrhythmia is recognized.

A subcutaneous ICD (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. The 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. Also, devices typically have approval in the secondary prevention setting for patients with previous myocardial infarction and reduced injection fraction.

**Summary**

An implantable cardioverter defibrillator (ICD) is a device designed to monitor a patient's heart rate, recognize ventricular fibrillation or ventricular tachycardia, and deliver an electric shock to terminate these arrhythmias to reduce the risk of sudden death. A subcutaneous ICD (S-ICD), which lacks transvenous leads, is intended to reduce lead-related complications.

**Transvenous Implantable Cardioverter Defibrillators**

For individuals who have a high-risk of sudden cardiac death (SCD) due to ischemic or to nonischemic cardiomyopathy in adulthood who receive transvenous ICD (TV-ICD) placement for primary prevention, the evidence includes multiple well-designed and well-conducted randomized controlled trials (RCTs) as well as systematic reviews of these trials. Relevant outcomes are overall survival (OS), 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 hypertrophic cardiomyopathy (HCM) in adulthood who receive TV-ICD placement for primary prevention, the evidence includes several large registry studies. Relevant outcomes are OS, 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 OS, 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 a high-risk of SCD due to cardiac sarcoid who receive TV-ICD placement for primary prevention, the evidence includes small cohort studies of patients with cardiac sarcoid treated with ICDs who received appropriate shocks. Studies comparing outcomes between patients treated and untreated with ICDs are not available. However, given the relatively small number of patients with cardiac sarcoid (5% of those with systemic sarcoiditis), clinical trials are unlikely. Given the long-term high-risk of SCD in patients with cardiac sarcoid, with the assumption that appropriate shocks are life-saving, these studies are considered adequate evidence to support the use of TV-ICDs in patients with cardiac sarcoid who have not responded to optimal medical therapy. 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 ventricular tachycardia or ventricular fibrillation (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 OS, 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 Implantable Cardioverter Defibrillators

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 OS, 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.

Clinical input was obtained in 2011 and 2015 on the use of ICDs in pediatric populations and for primary prevention in patients with cardiac ion channelopathies, and on the use of the S-ICD. For the use of ICDs in children with HCM or with a history of congenital heart disease, the evidence includes case series. These conditions have a low prevalence and heterogeneous patient populations, creating barriers to trials. There was a consensus that the use of ICDs in certain pediatric populations, consistent with
specialty society guidelines, is medically necessary. Indications for the use of ICDs to prevent SCD in HCM in pediatric patients parallel those in adults. There was also consensus that the use of an ICD should be considered medically necessary for primary prevention of ventricular arrhythmias in adults and children with a diagnosis of QTS, Brugada syndrome, short QT syndrome, or catecholaminergic polymorphic ventricular tachycardia. Criteria for determining patients at high-risk of SCD for the cardiac ion channelopathies was derived from clinical input and specialty society guidelines. There was a consensus that the use of an S-ICD should be considered medically necessary, particularly for patients with indications for an ICD but who have difficult vascular access (eg, children or patients undergoing chronic dialysis) or have had TV-ICD lead explantation due to complications.

### Policy History

<table>
<thead>
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<td>1/2021</td>
<td>Medicare information removed. See MP #132 Medicare Advantage Management for local coverage determination and national coverage determination reference.</td>
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<tr>
<td>1/2018</td>
<td>Clarified coding information.</td>
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<tr>
<td>7/2017</td>
<td>New references added from BCBSA National medical policy.</td>
</tr>
<tr>
<td>7/2016</td>
<td>New references added from BCBSA National medical policy.</td>
</tr>
<tr>
<td>3/2016</td>
<td>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.</td>
</tr>
<tr>
<td>1/2015</td>
<td>Clarified coding information.</td>
</tr>
<tr>
<td>6/2014</td>
<td>Updated Coding section with ICD10 procedure and diagnosis codes, effective 10/2015.</td>
</tr>
</tbody>
</table>

Information Pertaining to All Blue Cross Blue Shield Medical Policies

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


99. Khairy P, Van Hare GF, Balaji S, et al. PACES/HRS expert consensus statement on the recognition and management of arrhythmias in adult congenital heart disease: developed in partnership between the Pediatric and Congenital Electrophysiology Society (PACES) and the Heart Rhythm Society (HRS). Endorsed by the governing bodies of PACES, HRS, the American College of Cardiology (ACC), the American Heart Association (AHA), the European Heart Rhythm Association (EHRA), the Canadian Heart Rhythm Society (CHRS), and the International Society for Adult Congenital Heart Disease (ISACHD). Can J Cardiol. Oct 2014; 30(10): e1-e63. PMID 25262867