

Corporate Medical Policy

Implantable Cardioverter Defibrillator

File Name:	implantable_cardioverter_defibrillator
Origination:	10/2012
Last CAP Review:	06/2020
Next CAP Review:	06/2021
Last Review:	06/2020

Description of Procedure or Service

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

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 sudden cardiac death (SCD). Indications for ICD placement can be broadly subdivided into 1) secondary prevention, i.e., use in patients who have experienced a potentially life-threatening episode of VT (near SCD); and 2) primary prevention, i.e., 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 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 ICD (S-ICD) has also been developed. This device does not employ 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 that is 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 are approved by the U.S. Food and Drug Administration (FDA) through the premarket approval (PMA) 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. In addition, devices typically have approval in the secondary prevention setting in patients with a previous myocardial infarction (MI) and reduced ejection fraction.

NOTE: ICDs may be combined with other pacing devices, such as pacemakers for atrial fibrillation, or biventricular pacemakers designed to treat congestive heart failure. This policy addresses ICDs alone, when used solely to treat patients at risk for ventricular arrhythmias.

Related Policies:

Implantable Cardioverter Defibrillator

Wearable Cardioverter Defibrillators

*****Note: This Medical Policy is complex and technical. For questions concerning the technical language and/or specific clinical indications for its use, please consult your physician.**

Policy

BCBSNC will provide coverage for implantable cardioverter defibrillators when it is determined to be medically necessary because the medical criteria and guidelines noted below are met.

Benefits Application

This medical policy relates only to the services or supplies described herein. Please refer to the Member's Benefit Booklet for availability of benefits. Member's benefits may vary according to benefit design; therefore member benefit language should be reviewed before applying the terms of this medical policy.

When Implantable Cardioverter Defibrillators are covered

The use of an automatic implantable cardioverter defibrillator (ICD) may be considered medically necessary **in adult patients** 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 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 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 sarcoid and considered to be at high risk for sudden cardiac death

Secondary Prevention

Implantable Cardioverter Defibrillator

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

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;
- 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.

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 or biventricular pacing/resynchronization therapy; **AND**
- Do not have ventricular arrhythmias that are known or anticipated to respond to antitachycardia pacing.

When Implantable Cardioverter Defibrillators are not covered

Implantable Cardioverter Defibrillator

The use of the ICD is considered investigational in primary prevention patients who:

- have had an acute myocardial infarction (i.e., less than 40 days before ICD treatment);
- have New York Heart Association (NYHA) Class IV congestive heart failure (unless patient is eligible to receive a combination of cardiac resynchronization therapy ICD device);
- have had cardiac revascularization procedure past 3 months (CABG or 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.

The use of the ICD is considered investigational for all other indications in pediatric patients, except as outlined above.

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

Policy Guidelines

The evidence for transvenous implantable cardioverter defibrillator (TV-ICD) placement for primary prevention in individuals who have a high risk of sudden cardiac death (SCD) in adulthood due to ischemic or nonischemic cardiomyopathy (NICM), includes multiple well-designed, well-conducted randomized controlled trials (RCTs) and systematic reviews of these trials. Relevant outcomes are overall survival, morbid events, quality of life, and treatment-related morbidity and mortality. Multiple well-done RCTs have demonstrated a benefit in overall mortality for patients with ischemic cardiomyopathy and reduced ejection fraction. RCTs of early ICD implantation following recent MI did not support a benefit for immediate ICD implantation versus delayed implantation for at least 40 days. For non-ischemic cardiomyopathy (NICM), there is less clinical trial evidence available, but pooled estimates of available evidence from RCTs enrolling patients with NICM, and from subgroup analyses of RCTs with mixed populations, supports 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.

The evidence for TV-ICD placement for primary prevention in individuals who have a high risk of SCD in adulthood due to hypertrophic cardiomyopathy (HCM), includes several large registry studies. Relevant outcomes are overall survival, morbid events, quality of life, and treatment-related morbidity and mortality. In these studies, the annual rate of appropriate ICD discharge ranged from 3.6% to 5.3%. Given the long-term high risk of patients with HCM for SCD risk, with the assumption that appropriate shocks are life-saving, these rates are considered adequate evidence for 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.

The evidence for TV-ICD placement for primary prevention in individuals who have a high risk of SCD due to an inherited cardiac ion channelopathy, 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 morbidity and mortality. The limited available evidence for patients with long QT syndrome (LQTS), catecholaminergic polymorphic ventricular tachycardia (CPVT), and Brugada syndrome (BrS) reports high rates of appropriate shocks. No studies were identified on the use of ICDs for patients with short QT syndrome (SQTS). 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 for the use of TV-

Implantable Cardioverter Defibrillator

ICDs in patients with inherited cardiac ion channelopathies. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

The evidence for TV-ICD placement for primary prevention in individuals who have a high risk of SCD due to cardiac sarcoid, 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 individuals 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 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.

The evidence for TV-ICD placement in individuals who have had symptomatic life-threatening sustained VT/VF or have been resuscitated from sudden cardiac arrest (secondary prevention), includes multiple well-designed, well-conducted randomized controlled trials (RCTs) as well as systematic reviews of these trials. Relevant outcomes are overall survival, morbid events, quality of life, and treatment-related morbidity and mortality. Systematic reviews of RCTs have demonstrated a 25% reduction in mortality for ICD compared to 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.

The evidence for subcutaneous ICD (S-ICD) placement in individuals who need an ICD and have a contraindication to TV-ICD but no indications for antibradycardia pacing and no antitachycardia pacing-responsive arrhythmias, includes nonrandomized studies and case series. Relevant outcomes are overall survival, morbid events, quality of life, and treatment-related morbidity and mortality. 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 for 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.

The evidence for subcutaneous ICD (S-ICD) placement in individuals who have indications for a ICD without contraindications to TV-ICD, but no indications for antibradycardia pacing and no antitachycardia pacing-responsive arrhythmias, includes nonrandomized studies and case series. Relevant outcomes are overall survival, morbid events, quality of life, and treatment-related morbidity and mortality. Nonrandomized controlled studies report 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 of time. Case series report high rates of detection and successful conversion of VT, and inappropriate shock rates that are in the range reported for TV-ICD. This evidence is not sufficient to determine whether there are small differences in efficacy between the two types of devices, which may be clinically important due to the nature to the disorder being treated. Also, the adverse event rate is 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.

Billing/Coding/Physician Documentation Information

This policy may apply to the following codes. Inclusion of a code in this section does not guarantee that it will be reimbursed. For further information on reimbursement guidelines, please see Administrative Policies on the Blue Cross Blue Shield of North Carolina web site at www.bcsnc.com. They are listed in the Category Search on the Medical Policy search page.

Implantable Cardioverter Defibrillator

Applicable codes: 0571T, 0572T, 0573T, 0574T, 0575T, 0576T, 0577T, 0578T, 0579T, 0580T, 0614T, 33216, 33217, 33218, 33220, 33223, 33240, 33230, 33231, 33240, 33241, 33262, 33263, 33264, 33243, 33244, 33249, 93260, 93261, 93644

BCBSNC may request medical records for determination of medical necessity. When medical records are requested, letters of support and/or explanation are often useful, but are not sufficient documentation unless all specific information needed to make a medical necessity determination is included.

Scientific Background and Reference Sources

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Implantable Cardioverter Defibrillator

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Implantable Cardioverter Defibrillator

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Specialty Matched Consultant Advisory Panel review 6/2020

Medical Director review 6/2020

Policy Implementation/Update Information

10/01/12 New policy developed to separate information regarding Internal Cardioverter Defibrillators (ICD) from the External Defibrillator policy. BCBSNC will provide coverage for implantable cardioverter defibrillators when it is determined to be medically necessary because the medical criteria and guidelines are met. Medical Director review 9/2012. Policy notified on 10/1/2012 for effective date of 1/1/2013. (mco)

11/13/12 Revised information regarding the FDA approval for subcutaneous ICD. Policy effective date remains 1/1/2013. (mco)

7/16/13 Specialty Matched Consultant Advisory Panel 6/2013. Medical Director review 6/2013. (mco)

11/26/13 Description section updated. Policy Guidelines updated. References updated. (mco)

4/29/14 Revised "When Covered" section, under "Secondary Prevention" as follows: "Patients with a history of life-threatening clinical event associated with ventricular arrhythmic

Implantable Cardioverter Defibrillator

- events such as sustained ventricular tachyarrhythmia, **after reversible causes (e.g., acute ischemia) have been excluded.** References updated. (mco)
- 7/15/14 Specialty Matched Consultant Advisory Panel 6/2014. Medical Director review 6/2014. No changes to Policy Statements. (mco)
- 11/11/14 References updated. Policy Guidelines section updated. No changes to Policy Statements. (td)
- 12/30/14 Deleted CPT codes 0319T, 0320T, 0321T, 0322T, 0323T, 0324T, 0325T, 0326T, 0327T, 0328T and added CPT codes 33271, 33241, 33272, 33273, 93260, 93261, 93644 to the Billing/Coding section for effective date 1/1/2015. (td)
- 7/1/15 Description section updated to remove reference to an archived policy. (td)
- 10/1/15 Specialty Matched Consultant Advisory Panel review 6/24/15. Medical Director review. References updated. Policy intent unchanged. (td)
- 12/30/15 Description section updated. When Covered section updated to state “ICD medically necessary for patients with cardiac ion channelopathies with conditions; S-ICD medically necessary in limited situations”. When Not Covered sections updated. Policy Guidelines section updated. References updated. Senior Medical Director review 11/2015. (td)
- 4/1/16 When Not Covered section further clarified with the addition of this statement, “The use of the ICD for secondary prevention is considered investigational for patients who do not meet the criteria for primary prevention.” References updated. (td)
- 7/26/16 Description section updated and minor update to Policy Guidelines. References updated. Specialty Matched Consultant Advisory Panel review 6/29/16. Medical Director review. (jd)
- 6/30/17 Description section updated. Policy Guidelines and references updated. Medical Director review. (jd)
- 7/28/17 Specialty Matched Consultant Advisory Panel review 6/2017. Medical Director review 6/2017. (jd)
- 7/27/18 Specialty Matched Consultant Advisory Panel review 6/2018. Medical Director review 6/2018. (jd)
- 7/1/19 Related Policies section and references updated. Specialty Matched Consultant Advisory Panel review 6/2019. Medical Director review 6/2019. (jd)
- 12/31/19 The following codes were removed from the Billing/Coding section effective 10/1/2019: 33270, 33271, 33272, 33273; and the following codes were added effective 1/1/2020. (jd)
- 1/14/20 Minor update for clarification to indicate the codes that became effective 1/1/20 that are within the Billing/Coding section: 0571T, 0572T, 0573T, 0574T, 0575T, 0576T, 0577T, 0578T, 0579T, 0580T. (jd)
- 7/21/2020 Added last bullet when meeting medically necessary criteria as follows: “Diagnosis of cardiac sarcoid and considered to be at high risk for sudden cardiac death.” Policy guidelines updated. Added 0614T to the Billing/Coding section with effective date of 7/1/2020. References updated. Specialty Matched Consultant Advisory Panel review 6/2020. Medical Director review 6/2020. (jd)

Implantable Cardioverter Defibrillator

Medical policy is not an authorization, certification, explanation of benefits or a contract. Benefits and eligibility are determined before medical guidelines and payment guidelines are applied. Benefits are determined by the group contract and subscriber certificate that is in effect at the time services are rendered. This document is solely provided for informational purposes only and is based on research of current medical literature and review of common medical practices in the treatment and diagnosis of disease. Medical practices and knowledge are constantly changing and BCBSNC reserves the right to review and revise its medical policies periodically.