# Automatic Implantable Cardioverter Defibrillator (AICD)

**Policy #** 00008
Original Effective Date: 05/12/2003
Current Effective Date: 09/13/2021

*Applies to all products administered or underwritten by Blue Cross and Blue Shield of Louisiana and its subsidiary, HMO Louisiana, Inc.(collectively referred to as the "Company"), unless otherwise provided in the applicable contract. Medical technology is constantly evolving, and we reserve the right to review and update Medical Policy periodically.*

*Note: "Biventricular Pacemakers for the Treatment of Congestive Heart Failure." is addressed in medical policy 00009.*

# When Services May Be Eligible for Coverage

*Coverage for eligible medical treatments or procedures, drugs, devices or biological products may be provided only if:*

- *Benefits are available in the member's contract/certificate, and*
- *Medical necessity criteria and guidelines are met.*

**TRANSVENOUS ICD**

**Adults**

Based on review of available data, the Company may consider the use of an automatic implantable cardioverter defibrillator (AICD) in adults to be **eligible for coverage.****

**Primary Prevention**

Patient Selection Criteria

Coverage eligibility for the use of an automatic implantable cardioverter defibrillator (AICD) in adults will be considered when the following criteria are met:

- Ischemic cardiomyopathy with New York Heart Association functional Class II or Class III symptoms, a history of myocardial infarction at least 40 days before automatic implantable cardioverter defibrillator (AICD) treatment, and left ventricular ejection fraction (LVEF) of 35% or less; OR
- Ischemic cardiomyopathy with New York Heart Association functional Class I symptoms, a history of myocardial infarction at least 40 days before automatic implantable cardioverter defibrillator (AICD) treatment, and left ventricular ejection fraction (LVEF) of 30% or less; OR

- Nonischemic dilated cardiomyopathy and left ventricular ejection fraction (LVEF) of 35% or less, after reversible causes have been excluded, and the response to optimal medical therapy has been adequately determined; OR
- Hypertrophic cardiomyopathy with 1 or more major risk factors for sudden cardiac death (history of premature hypertrophic cardiomyopathy-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 nonsustained 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 hypertrophic cardiomyopathy.
- Spontaneous sustained ventricular tachycardia (VT persisting for at least 30 seconds or requiring termination due to hemodynamic compromise) in a patient with structural heart disease
- Diagnosis of any one of the following cardiac ion channelopathies and considered to be at high risk for sudden cardiac death (see Policy Guidelines section):
    - 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 (see Policy Guidelines section)

**Secondary Prevention**

Patient Selection Criteria

Coverage eligibility for the use of an automatic implantable cardioverter defibrillator (AICD) in adults will be considered when the following criteria are met:

- As a secondary prevention for 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.

# When Services Are Considered Investigational

*Coverage is not available for investigational medical treatments or procedures, drugs, devices or biological products.*

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Based on review of available data, the Company may consider the use of an automatic implantable cardioverter defibrillator (AICD) in adults for primary prevention patients in the following situations to be **investigational*:**

- Have had an acute myocardial infarction (i.e., less than 40 days before automatic implantable cardioverter defibrillator (AICD) treatment);
- Have New York Heart Association Class IV congestive heart failure (unless patient is eligible to receive a combination cardiac resynchronization therapy automatic implantable cardioverter defibrillator device [AICD]);
- Have had cardiac revascularization procedure in past three months (coronary artery bypass graft [CABG] or percutaneous transluminal coronary angioplasty) or are candidates for a cardiac revascularization procedure; or
- Have noncardiac disease that would be associated with life expectancy less than one year.

Based on review of available data, the Company considers the use of an automatic implantable cardioverter defibrillator (AICD) when patient selection criteria are not met to be **investigational.***

Based on review of available data, the Company considers use of the automatic implantable cardioverter defibrillator (AICD) for secondary prevention in patients who do not meet the criteria for secondary prevention to be **investigational.***

**PEDIATRICS**

# When Services May Be Eligible for Coverage

Coverage for eligible medical treatments or procedures, drugs, devices or biological products may be provided only if:

- Benefits are available in the member's contract/certificate, and
- Medical necessity criteria and guidelines are met.

Based on review of available data, the Company may consider use of an automatic implantable cardioverter defibrillator (AICD) in children who meet any of the following criteria to be **eligible for coverage**:**

- 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 (see Policy Guidelines):
    - Congenital long QT syndrome (LQTS); OR
    - Brugada syndrome (BrS); OR
    - Short QT syndrome (SQTS); OR
    - Catecholaminergic polymorphic ventricular tachycardia (CPVT).

# When Services Are Considered Investigational

Coverage is not available for investigational medical treatments or procedures, drugs, devices or biological products.

Based on review of available data, the Company considers the use of the automatic implantable cardioverter defibrillator (AICD) for all other indications in pediatric patients to be **investigational.***

**SUBCUTANEOUS ICD**

# When Services May Be Eligible for Coverage

Coverage for eligible medical treatments or procedures, drugs, devices or biological products may be provided only if:

- Benefits are available in the member's contract/certificate, and
- Medical necessity criteria and guidelines are met.

Based on review of available data, the Company may consider the use of a subcutaneous implantable cardioverter defibrillator (ICD) to be **eligible for coverage**** in 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 anti-bradycardia pacing; AND
- Do not have ventricular arrhythmias that are known or anticipated to respond to anti-tachycardia pacing.

# When Services Are Considered Investigational

Coverage is not available for investigational medical treatments or procedures, drugs, devices or biological products.

Based on review of available data, the Company considers the use of a subcutaneous implantable cardioverter defibrillator (ICD) for individuals who do not meet the criteria outlined above to be **investigational.***

# Policy Guidelines

This evidence review addresses the use of implantable cardioverter defibrillator (ICD) devices as stand-alone interventions, not as combination devices to treat heart failure (ie, cardiac resynchronization devices) or in combination with pacemakers. Unless specified, the policy statements and rationale refer to transvenous ICDs.

Indications for pediatric ICD use are based on American College of Cardiology (ACC), American Heart Association (AHA), and Heart Rhythm Society (HRS) guidelines published in 2008 (updated in 2012), which acknowledged the lack of primary research on pediatric patients in this field (see Rationale section). These indications derive from nonrandomized studies, extrapolation from adult clinical trials, and expert consensus.

**Criteria for Implantable Cardioverter Defibrillator 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 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.

NOTE: For congenital LQTS, patients may have 1 or more clinical or historical findings other than those outlined above that could, alone or in combination, put them at higher risk for sudden cardiac death. They can include patients with a family history of sudden cardiac death due to LQTS, infants with a diagnosis of LQTS with functional 2:1 atrioventricular block, patients with a diagnosis of LQTS in conjunction with a diagnosis of Jervell and Lange-Nielsen syndrome or Timothy syndrome, and patients with a diagnosis of LQTS with profound QT prolongation (>550 ms). These factors should be evaluated on an individualized basis by a clinician with expertise in LQTS when considering the need for ICD placement.

**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
    - syncope or near-syncope, felt to be arrhythmic in etiology OR
    - evidence of myocardial scar by cardiac MRI or positron emission tomographic (PET) scan OR

  - Inducible sustained ventricular arrhythmias (>30 seconds of monomorphic VT or polymorphic VT) or clinically relevant VF
- An indication for permanent pacemaker implantation.

# Background/Overview

**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.

# FDA or Other Governmental Regulatory Approval

**U.S. Food and Drug Administration (FDA)**

**Transvenous Implantable Cardioverter Defibrillators**

A large number of ICDs have been approved by the FDA through the premarket approval (PMA) process (FDA product code: LWS). A 2014 review of the FDA approvals of cardiac implantable devices reported that, between 1979 and 2012, the FDA approved 19 ICDs (7 pulse generators, 3 leads, 9 combined systems) through new PMA applications. Many originally approved ICDs have received multiple supplemental applications. A selective summary of some currently available ICDs is provided in Table 1.

**Subcutaneous Implantable Cardioverter Defibrillators**

In 2012, the Subcutaneous Implantable Defibrillator (S-ICD™)‡ System was approved by the FDA through the PMA process for the treatment of life-threatening ventricular tachyarrhythmias in patients who do not have symptomatic bradycardia, incessant VT, or spontaneous, frequently recurring VT that is reliably terminated with antitachycardia pacing (see Table 1).

In 2015, the Emblem™‡ S-ICD (Boston Scientific), which is smaller and longer-lasting than the original S-ICD, was approved by the FDA through the PMA supplement process.

In February 2021, Boston Scientific issued a recall of the Emblem S-ICD because of increased risk of device fractures. FDA designated the recall a Class I event, the most serious type of recall, indicating a situation in which there is a reasonable probability that the use of the device may cause serious injuries or death.

**Table 1. Implantable Cardioverter Defibrillators with FDA Approval**

| Device | Manufacturer | Original PMA Approval Date |
|---|---|---|
| Transvenous | | |
| Ellipse™/Fortify Assura™ Family (originally: Cadence Tiered Therapy Defibrillation System) | St. Jude Medical | Jul 1993 |
| Current® Plus ICD (originally: Cadence Tiered Therapy Defibrillation System) | St. Jude Medical | Jul 1993 |
| Dynagen™, Inogen™, Origen™, and Teligen® Family (originally: Ventak, Vitality, Cofient family) | Boston Scientific | Jan 1998 |
| Evera™ Family (originally: Virtuosos/Entrust/Maximo/ Intrisic/Marquis family) | Medtronic | Dec 1998 |
| Subcutaneous | | |
| Subcutaneous Implantable Defibrillator System (S-ICD ) | Cameron Health; acquired by Boston Scientific | Sep 2012 |

FDA: Food and Drug Administration; PMA: premarket application.

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

# Rationale/Source

An 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.

For individuals who need an ICD and have no indications for antibradycardia pacing or antitachycardia pacing-responsive arrhythmias and have no contraindication to a T-ICD, who receive S-ICD placement, the evidence includes 1 RCT, nonrandomized studies and case series. Relevant outcomes are OS, morbid events, quality of life, and treatment-related mortality and morbidity. The PRAETORIAN (Prospective, Randomized Comparison of Subcutaneous and Transvenous Implantable Cardioverter Defibrillator Therapy) trial is the only RCT on the effect of an S-ICD with health outcomes. PRAETORIAN found that S-ICD was noninferior to T-ICD on a composite outcome of complications and inappropriate shock at 48 months (hazard ratio 0.99; 95% confidence interval, 0.71 to 1.39; noninferiority margin, 1.45; p =.01 for noninferiority; p =.95 for superiority). There were more device related complications in the T-ICD group and more inappropriate shocks in the S-ICD group, but the trial was not powered for these endpoints. There is uncertainty over the applicability and interpretation of PRAETORIAN based on the choice of a composite outcome with discordant results, unclear rationale for choice of the noninferiority margin, inadequate length of follow up to determine rates of complications, and lack of reporting of quality of life data. Comparative observational studies are insufficient to draw conclusions on whether there are small differences in efficacy between the two types of devices, and reported variable adverse event rates. Ongoing studies could provide additional evidence on complications and device safety over the longer term. The evidence is insufficient to determine that the technology results in an 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.

In October 2020, the BCBSA Medical Advisory Panel (MAP) reviewed the evidence for individuals who need an ICD and have no contraindication to transvenous ICD placement and agreed that for this indication, the evidence is insufficient to determine the effects of the technology on health outcomes.

# Supplemental Information

**Clinical Input From Physician Specialty Societies and Academic Medical Centers**

While the various physician specialty societies and academic medical centers may collaborate with and make recommendations during this process through the provision of appropriate reviewers, input received does not represent an endorsement or position statement by the physician specialty societies or academic medical centers, unless otherwise noted.

**2020 Medical Advisory Panel**

In October 2020, the BCBSA Medical Advisory Panel (MAP) reviewed the evidence for individuals who need an ICD and have no contraindication to transvenous ICD placement and agreed that for this indication, the evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

**2015 Input**

In response to requests, input was received from 1 physician specialty society (4 responses) and 5 academic medical centers, for a total of 9 responses, while this policy was under review in 2015. Input focused on the use of ICDs as primary prevention for cardiac ion channelopathies and use of the subcutaneous implantable cardioverter defibrillator. Reviewers generally indicated that an ICD should be considered medically necessary for primary prevention of ventricular arrhythmias in adults and children with a diagnosis of long QT syndrome, Brugada syndrome, short QT syndrome, and catecholaminergic polymorphic ventricular tachycardia. Reviewers generally indicated that the subcutaneous implantable cardioverter defibrillator should be considered medically necessary

particularly for patients with indications for an ICD but who have difficult vascular access or have had transvenous ICD lead explantation due to complications.

**2011 Input**
In response to requests, input was received from 6 academic medical centers while this policy was under review in 2011. For most policy indications, including pediatric, there was general agreement from those providing input. On the question of timing of ICD placement, input was mixed, with some commenting about the potential role of early implantation in select patients. Reviewers indicated that a waiting period of nine months for patients with nonischemic cardiomyopathy was not supported by the available evidence or consistent with the prevailing practice patterns in academic medical centers. Input emphasized the difficulty of prescribing strict timeframes given the uncertainty of establishing the onset of cardiomyopathy and the inability to risk-stratify patients based on time since onset of cardiomyopathy.

**Practice Guidelines and Position Statements**
Guidelines or position statements will be considered for inclusion in 'Supplemental Information' if they were issued by, or jointly by, a US professional society, an international society with US representation, or National Institute for Health and Care Excellence (NICE). Priority will be given to guidelines that are informed by a systematic review, include strength of evidence ratings, and include a description of management of conflict of interest.

***American Heart Association, American College of Cardiology, and Heart Rhythm Society Guidelines on Heart Failure (2017)***
The AHA, American College of Cardiology, and Heart Rhythm Society (HRS) (2017) published joint guidelines on the management of heart failure, which updated their 2012 guidelines. These guidelines made the following recommendations on the use of ICD devices (see Tables 2-9). The recommendations for the use of an ICD apply only if meaningful survival is expected to be greater than 1 year.

**Table 2. Guidelines on Device-Based Therapy of Cardiac Rhythm Abnormalities**

| Recommendation | COR | LOE |
|---|---|---|

| | | |
|---|---|---|
| "In patients with ischemic heart disease, who either survive SCA due to VT/VF or experience hemodynamically unstable VT (LOE: B-R) or stable VT (LOE: B-NR) not due to reversible causes..." | I | B-R B-NR |
| "A transvenous ICD provides intermediate value in the secondary prevention of SCD particularly when the patient's risk of death due to a VA is deemed high and the risk of nonarrhythmic death (either cardiac or noncardiac) is deemed low based on the patient's burden of comorbidities and functional status." | | B-R |
| "In patients with ischemic heart disease and unexplained syncope who have inducible sustained monomorphic VT on electrophysiological study..." | I | B-NR |
| "In patients resuscitated from SCA due to coronary artery spasm in whom medical therapy is ineffective or not tolerated..." | IIa | B-NR |
| "In patients resuscitated from SCA due to coronary artery spasm, an ICD in addition to medical therapy may be reasonable..." | IIb | B-NR |
| "In patients with arrhythmogenic right ventricular cardiomyopathy and an additional marker of increased risk of SCD (resuscitated SCA, sustained VT, significant ventricular dysfunction with RVEF or LVEF ≤35%)." | I | B-NR |
| "In patients with arrhythmogenic right ventricular cardiomyopathy and syncope presumed due to VA..." | IIa | B-NR |

B-NR: moderate, non-randomized; B-R: moderate, randomized; COR: class of recommendation; ICD: implantable cardioverter defibrillator; LOE: level of evidence; LVEF: left ventricular ejection fraction; RVEF: right ventricular ejection fraction; SCA: sudden cardiac arrest; SCD: sudden cardiac death; VA: ventricular arrhythmia; VF: ventricular fibrillation; VT: ventricular tachycardia.

**Table 3. Guidelines on Use of ICDs as a Primary Prevention of Ischemic Heart Disease**

| Recommendation | COR | LOE |
|---|---|---|
| "In patients with LVEF of 35% or less that is due to ischemic heart disease who are at least 40 days' post-MI and at least 90 days post revascularization, and with NYHA class II or III HF despite GDMT..." | I | A |

| | | |
|---|---|---|
| " In patients with LVEF of 30% or less that is due to ischemic heart disease who are at least 40 days' post-MI and at least 90 days post revascularization, and with NYHA class I HF despite GDMT..." | I | A |
| "A transvenous ICD provides high value in the primary prevention of SCD particularly when the patient's risk of death due to a VA is deemed high and the risk of nonarrhythmic death (either cardiac or noncardiac) is deemed low based on the patient's burden of comorbidities and functional status..." | | B-R |
| "In patients with NSVT due to prior MI, LVEF of 40% or less and inducible sustained VT or VF at electrophysiological study..." | I | B-R |
| "In nonhospitalized patients with NYHA class IV symptoms who are candidates for cardiac transplantation or an LVAD..." | IIa | B-NR |
| "An ICD is not indicated for NYHA class IV patients with medication-refractory HF who are not also candidates for cardiac transplantation, an LVAD, or a CRT defibrillator that incorporates both pacing and defibrillation capabilities." | III[a] | C-EO |

A: high; B-NR: moderate, non-randomized; B-R: moderate, randomized; C-EO: consensus of experte opinion; CRT: cardiac resynchronization therapy; COR: class of recommendation; ICD: implantable cardioverter defibrillator; GDMT: guideline-directed management and therapy; HF: heart failure; LOE: level of evidence; LVAD: left ventricular assist device; LVEF: left ventricular ejection fraction; MI: myocardial infarction; NSVT: nonsustained ventricular tachycardia; NYHA: New York Heart Association; SCD: sudden cardiac death; VA: ventricular arrhythmia; VF: ventricular fibrillation; VT: ventricular tachycardia.
a No benefit.

**Table 4. Guidelines on Use of ICDs for Nonischemic Cardiomyopathy**

| Recommendation | COR | LOE |
|---|---|---|
| "In patients with NICM who either survive SCA due to VT/VF or experience hemodynamically unstable VT (LOE: B-R) (1-4) or stable VT (LOE: B-NR) (5) not due to reversible causes..." | I | B-R B-NR |

| | | |
|---|---|---|
| " In patients with NICM who experience syncope presumed to be due to VA and who do not meet indications for a primary prevention ICD, an ICD or an electrophysiological study for risk stratification for SCD can be beneficial..." | IIa | B-NR |
| "In patients with NICM, HF with NYHA class II-III symptoms and an LVEF of 35% or less, despite GDMT..." | IIa | B-R |
| "In patients with NICM, HF with NYHA class I symptoms and an LVEF of 35% or less, despite GDMT..." | IIb | B-R |
| "In patients with medication-refractory NYHA class IV HF who are not also candidates for cardiac transplantation, an LVAD, or a CRT defibrillator that incorporates both pacing and defibrillation capabilities, an ICD should not be implanted." | III[a] | C-EO |

A: high; B-NR: moderate, non-randomized; B-R: moderate, randomized; C-EO: consensus of experte opinion; COR: class of recommendation; CRT: cardiac resynchronization therapy; GDMT: guideline-directed management and therapy; HF: heart failure; ICD: implantable cardioverter defibrillator: LOE: level of evidence; LVAD: left ventricular assist device; LVEF: left ventricular ejection fraction; NICM: nonischemic cardiomyopathy; NYHA: New York Heart Association; SCA: sudden cardiac arrest; SCD: sudden cardiac death; VA: ventricular arrhythmia; VF: ventricular fibrillation; VT: ventricular tachycardia.
a No benefit.

**Table 5. Guidelines on Use of ICDs for HCM**

| **Recommendation** | **COR** | **LOE** |
|---|---|---|
| "In patients with HCM who have survived an SCA due to VT or VF, or have spontaneous sustained VT causing syncope or hemodynamic compromise..." | I | B-NR |
| "In patients with HCM and 1 or more of the following risk factors...<br>• Maximum LV wall thickness ≥30 mm (LOE: B-NR).<br>• SCD in 1 or more first-degree relatives presumably caused by HCM (LOE: C-LD). | IIa | B-NR<br>C-LD |

| | | |
|---|---|---|
| • 1 or more episodes of unexplained syncope within the preceding 6 months (LOE: C-LD)" | | C-LD |
| "In patients with HCM who have spontaneous NSVT (LOE: C-LD) or an abnormal blood pressure response with exercise (LOE: B-NR), who also have additional SCD risk modifiers or high risk features..." | IIa | B-NR C-LD |
| "In patients with HCM who have NSVT (LOE: B-NR) or an abnormal blood pressure response with exercise (LOE: B-NR) but do not have any other SCD risk modifiers, an ICD may be considered, but its benefit is uncertain." | IIB | B-NR B-NR |
| "In patients with an identified HCM genotype in the absence of SCD risk factors, an ICD should not be implanted" | III[a] | B-NR |

B-NR: moderate, non-randomized; C-LD: limited data; COR: class of recommendation; HCM: hypertrophic cardiomyopathy; ICD: implantable cardioverter defibrillator; LOE: level of evidence; LV: left ventricular; NSVT: nonsustained ventricular tachycardia; SCA: sudden cardiac arrest; SCD: sudden cardiac death; VF: ventricular fibrillation; VT: ventricular tachycardia.
a No benefit.

**Table 6. Guidelines on Use of Subcutaneous ICDs for Cardiac Sarcoiditis**

| Recommendation | COR | LOE |
|---|---|---|
| "In patients with cardiac sarcoidosis who have sustained VT or are survivors of SCA or have an LVEF of 35% or less, an ICD is recommended, if meaningful survival of greater than 1 year is expected." | I | B-NR |
| "In patients with cardiac sarcoidosis and LVEF greater than 35% who have syncope and/or evidence of myocardial scar by cardiac MRI or positron emission tomographic (PET) scan, and/or have an indication for permanent pacing, implantation of an ICD is reasonable, provided that meaningful survival of greater than 1 year is expected." | IIa | B-NR |

| | | |
|---|---|---|
| "In patients with cardiac sarcoidosis and LVEF greater than 35%, it is reasonable to perform an electrophysiological study and to implant an ICD, if sustained VA is inducible, provided that meaningful survival of greater than 1 year is expected." | IIa | C-LD |
| "In patients with cardiac sarcoidosis who have an indication for permanent pacing, implantation of an ICD can be beneficial." | IIa | C-LD |

B-NR: moderate, non-randomized; C-LD: limited data; COR: class of recommendation; ICD: implantable cardioverter defibrillator; LOE: level of evidence; LVEF: left ventricular ejection fraction; MRI: magnetic resonance imaging; SCA: sudden cardiac arrest; VA: ventricular arrhythmia; VT: ventricular tachycardia.

**Table 7. Guidelines on Use of ICDs for Other Conditions**

| Recommendation | COR | LOE |
|---|---|---|
| "In patients with HFrEF who are awaiting heart transplant and who otherwise would not qualify for an ICD (e.g., NYHA class IV and/or use of inotropes) with a plan to discharge home, an ICD is reasonable" | IIa | B-NR |
| "In patients with an LVAD and sustained VA, an ICD can be beneficial." | IIa | C-LD |
| "In patients with a heart transplant and severe allograft vasculopathy with LV dysfunction..." | IIb | B-NR |
| "In patients with neuromuscular disorders, primary and secondary prevention ICDs are recommended for the same indications as for patients with NICM..." | I | B-NR |
| In patients with a cardiac channelopathy (see Guideline Tables 7.9 and 7.9.1) | I | B-NR |
| In patients with catecholaminergic polymorphic ventricular tachycardia and recurrent sustained VT or syncope (see Guideline Table 7.9.1.2) | I | B-NR |
| "In patients with Brugada syndrome with spontaneous type 1 Brugada electrocardiographic pattern and cardiac arrest, sustained VA or a recent history of syncope presumed due to VA..." | I | B-NR |

| | | |
|---|---|---|
| "In patients with early repolarization pattern on ECG and cardiac arrest or sustained VA..." | I | B-NR |
| "In patients resuscitated from SCA due to idiopathic polymorphic VT or VF..." | I | B-NR |
| "For older patients and those with significant comorbidities, who meet indications for a primary prevention ICD, an ICD is reasonable." | IIa | B-NR |
| "In patients with adult congenital heart disease with SCA due to VT or VF in the absence of reversible causes..." | I | B-NR |
| "In patients with repaired moderate or severe complexity adult congenital heart disease with unexplained syncope and at least moderate ventricular dysfunction or marked hypertrophy, either ICD implantation or an electrophysiological study with ICD implantation for inducible sustained VA is reasonable..." | IIa | B-NR |

B-NR: moderate, non-randomized; C-LD: limited data; COR: class of recommendation; ECG: electrocardiogram; HFrEF; heart failure with reduced ejection fraction; ICD: implantable cardioverter defibrillator; LOE: level of evidence; LV: left ventricle; LVAD: left ventricular assist device; NICM: nonischemic cardiomyopathy; NYHA: New York Heart Association; SCA: sudden cardiac arrest; VA: ventricular arrhythmia; VF: ventricular fibrillation; VT: ventricular tachycardia.

**Table 8. Guidelines on Use of Subcutaneous ICDs**

| **Recommendation** | **COR** | **LOE** |
|---|---|---|
| "In patients who meet criteria for an ICD who have inadequate vascular access or are at high risk for infection, and in whom pacing for bradycardia or VT termination or as part of CRT is neither needed nor anticipated, a subcutaneous implantable cardioverter-defibrillator is recommended." | I | B-NR |
| "In patients who meet indication for an ICD, implantation of a subcutaneous implantable cardioverter-defibrillator is reasonable if pacing for bradycardia or VT termination or as part of CRT is neither needed nor anticipated." | IIa | B-NR |

| | | |
|---|---|---|
| "In patients with an indication for bradycardia pacing or CRT, or for whom antitachycardia pacing for VT termination is required, a subcutaneous implantable cardioverter-defibrillator should not be implanted." | III[a] | B-NR |

B-NR: moderate, non-randomized; CRT: cardiac resynchronization therapy; COR: class of recommendation; ICD: implantable cardioverter defibrillator; LOE: level of evidence; VT: ventricular tachycardia.
a Harm.

The 2013 update made the following recommendations on ICD therapy for children (see Table 9).

**Table 9. Guidelines on ICD Therapy for Children**

| Recommendation | COR | LOE |
|---|---|---|
| ICD implantation is indicated in the survivor of cardiac arrest after evaluation to define the cause of the event and to exclude any reversible causes. | I | B |
| ICD implantation is indicated for patients with symptomatic sustained VT in association with congenital heart disease who have undergone hemodynamic and electrophysiological evaluation. Catheter ablation or surgical repair may offer possible alternatives in carefully selected patients. | I | C |
| ICD implantation is reasonable for patients with congenital heart disease with recurrent syncope of undetermined origin in the presence of either ventricular dysfunction or inducible ventricular arrhythmias at electrophysiological study. | IIa | B |
| ICD implantation may be considered for patients with recurrent syncope associated with complex congenital heart disease and advanced systemic ventricular dysfunction when thorough invasive and noninvasive investigations have failed to define a cause. | IIb | C |
| All class III recommendations found in Section 3, "Indications for Implantable Cardioverter-Defibrillator Therapy," apply to pediatric patients and patients with congenital heart disease, and ICD implantation is not indicated in these patient populations. | III[a] | C |

COR: class of recommendation; ICD: implantable cardioverter defibrillator; LOE: level of evidence; VT: ventricular tachycardia.
a Not recommended.

**American Heart Association/American College of Cardiology Guidelines on Hypertrophic Cardiomyopathy (2020)**

In 2020, the American Heart Association and American College of Cardiology published a joint Guideline for the Diagnosis and Treatment of Patients with Hypertrophic Cardiomyopathy. Recommendations relevant to this review are summarized in Table 10.

**Table 10. Patients Selection for ICD Placement in High-Risk Patients With Hypertrophic Cardiomyopathy**

| Recommendation | COR | LOE |
|---|---|---|
| For patients with HCM, and previous documented cardiac arrest or sustained ventricular tachycardia, ICD placement is recommended. | I | B-NR |
| For adult patients with HCM with 1 or more major risk factors for SCD, it is reasonable to offer an ICD | 2a | B-NR |
| For children with HCM who have 1 or more conventional risk factors, ICD placement is reasonable after considering th relatively high complication rates of long-term ICD placement in younger patients | 2a | B-NR |
| For patients 16 years and older with HCM and 1 or more major SCD risk factors, discussion of the estimated 5-year sudden death risk and mortality rates can be useful during the shared decision-making process for ICD placement | 2a | B-NR |
| In patients with HCM without risk factors, ICD placement should not be performed | 3: Harm | B-NR |
| In patients with HCM, ICD placement for the sole purpose of participation in competitive athletics should not be performed | 3: Harm | B-NR |
| In patients with hypertrophic cardiomyopathy who are receiving an ICD, either a single chamber transvenous ICD or a subcutaneous ICD is recommended after a shared decision-making discussion that takes into consideration patient | I | B-NR |

| | | |
|---|---|---|
| preferences, lifestyle, and expected potential need for pacing for bradycardia or ventricular tachycardia termination | | |

B-NR: moderate, non-randomized; COR: class of recommendation; HCM: hypertrophic cardiomyopathy; ICD: implantable cardioverter defibrillator; LOE: level of evidence; SCD: sudden cardiac death.

**ICD Therapy in Patients Not Well Represented in Clinical Trials**

The HRS, the American College of Cardiology, and AHA (2014) published an expert consensus statement on the use of ICD therapy for patients not included or poorly represented in ICD clinical trials. The statement presented a number of consensus-based guidelines on the use of ICDs in select patient populations.

**American Heart Association**

AHA (2010) issued a scientific statement, endorsed by HRS, on cardiovascular implantable electronic device infections and their management. This statement made the following recommendations on the removal of device-related infections (see Table 11).

**Table 11. Guidelines on the Management of CIED Infections**

| Recommendation | COR | LOE |
|---|---|---|
| Complete device and lead removal is recommended for all patients with definite CIED infection, as evidenced by valvular and/or lead endocarditis or sepsis. | I | A |
| Complete device and lead removal is recommended for all patients with CIED pocket infection as evidenced by abscess formation, device erosion, skin adherence, or chronic draining sinus without clinically evident involvement of the transvenous portion of the lead system. | I | B |
| Complete device and lead removal is recommended for all patients with valvular endocarditis without definite involvement of the lead(s) and/or device. | I | B |
| Complete device and lead removal is recommended for patients with occult staphylococcal bacteremia. | I | B |

CIED: cardiovascular implantable electronic device; COR: class of recommendation; LOE: level of evidence.

**Heart Rhythm Society- Arrhythmogenic Cardiomyopathy**
In 2019, the HRS published a consensus statement on evaluation, risk stratification, and management of arrhythmogenic cardiomyopathy. Recommendations related to ICD risk stratification and placement decisions are shown in Table 12.

**Table 12. Guidelines on Risk Stratification and ICD Decisions**

| Recommendation | COR[1] | LOE[2] |
|---|---|---|
| In individuals with ARVC with hemodynamically tolerated sustained VT, an ICD is reasonable. | IIa | B-NR |
| ICD implantation is reasonable for individuals with ARVC and three major, two major and two minor, or one major and four minor risk factors for ventricular arrhythmia. | IIa | B-NR |
| ICD implantation may be reasonable for individuals with ARVC and two major, one major and two minor, or four minor risk factors for ventricular arrhythmia. | IIb | B-NR |
| In individuals with ACM with LVEF 35% or lower and NYHA class II-III symptoms and an expected meaningful survival of greater than 1 year, an ICD is recommended. | I | B-R |
| In individuals with ACM with LVEF 35% or lower and NYHA class I symptoms and an expected meaningful survival of greater than 1 year, an ICD is reasonable. | IIa | B-R |
| In individuals with ACM (other than ARVC) and hemodynamically tolerated VT, an ICD is recommended. | I | B-NR |
| In individuals with phospholamban cardiomyopathy and LVEF <45% or NSVT, an ICD is reasonable. | IIa | B-NR |
| In individuals with lamin A/C ACM and two or more of the following: LVEF <45%, NSVT, male sex, an ICD is reasonable. | IIa | B-NR |
| In individuals with FLNC ACM and an LVEF <45%, an ICD is reasonable. | IIa | C-LD |

| | | |
|---|---|---|
| In individuals with lamin A/C ACM and an indication for pacing, an ICD with pacing capabilities is reasonable. | IIa | C-LD |

ACM: arrhythmogenic cardiomyopathy;ARVC: arrhythmogenic right ventricular cardiomyopathy;COR: Class of Recommendation;FLNC: filamin-C; ICD: Implantable cardioverter defibrillator; LOE: Level of Evidence; LVEF: left ventricular ejection fraction; NSVT: nonsustained ventricular tachycardia; NYHA: New York Heart Association; VT: ventricular tachycardia. [1] Class I: Strong; Class IIa: Moderate; Class IIb: Weak. [2] B-R: Randomized; B-NR: nonrandomized; C-LD: limited data

**Heart Rhythm Society et al- Inherited Primary Arrhythmia Syndromes**

The HRS, the European Heart Rhythm Association, and the Asia-Pacific Heart Rhythm Society (2013) issued a consensus statement on the diagnosis and management of patients with inherited primary arrhythmia syndromes, which included recommendations on ICD use in patients with long QT syndrome, Brugada syndrome, catecholaminergic polymorphic ventricular tachycardia, and short QT syndrome (see Table 13).

**Table 13. Guidelines on the Diagnosis and Management of Inherited Primary Arrhythmia Syndromes**

| **Recommendation** | **COR** |
|---|---|
| Long QT syndrome | |
| ICD implantation is recommended for patients with a diagnosis of LQTS who are survivors of a cardiac arrest | I |
| ICD implantation can be useful in patients with a diagnosis of LQTS who experience recurrent syncopal events while on beta-blocker therapy | IIa |
| Except under special circumstances, ICD implantation is not indicated in asymptomatic LQTS patients who have not been tried on beta-blocker therapy | III[a] |
| Brugada syndrome | |
| ICD implantation is recommended in patients with a diagnosis of BrS who:<br>• Are survivors of a cardiac arrest and/or | I |

| | |
|---|---|
| • Have documented spontaneous sustained VT with or without syncope. | |
| ICD implantation can be useful in patients with a spontaneous diagnostic type I ECG who have a history of syncope judged to be likely caused by ventricular arrhythmias. | IIa |
| ICD implantation may be considered in patients with a diagnosis of BrS who develop VF during programmed electrical stimulation (inducible patients). | IIb |
| ICD implantation is not indicated in asymptomatic BrS patients with a drug-induced type I ECG and on the basis of a family history of SCD alone. | III[a] |
| Catecholaminergic polymorphic ventricular tachycardia | |
| ICD implantation is recommended for patients with a diagnosis of CPVT who experience cardiac arrest, recurrent syncope or polymorphic/bidirectional VT despite optimal medical management, and/or left cardiac sympathetic denervation. | I |
| ICD as a standalone therapy is not indicated in an asymptomatic patient with a diagnosis of CPVT | III[a] |
| Short QT syndrome | |
| ICD implantation is recommended in symptomatic patients with a diagnosis of SQTS who:Are survivors of cardiac arrest and/orHave documented spontaneous VT with or without syncope. | I |
| ICD implantation may be considered in asymptomatic patients with a diagnosis of SQTS and a family history of sudden cardiac death. | IIb |

BrS: Brugada syndrome; COR: class of recommendation; CPVT: catecholaminergic polymorphic ventricular tachycardia; ECG: electrocardiogram; ICD: implantable cardioverter defibrillator; LQTS: long QT syndrome; SCD: sudden cardiac death; SQTS: short QT syndrome; VF: ventricular fibrillation; VT: ventricular tachycardia.
a Not recommended.

ICD implantation may be considered in patients with LVEF in the range of 36%–49% and/or RV ejection fraction <40%, despite optimal medical therapy and a period of immunosuppression (if indicated).

**Heart Rhythm Society - Cardiac Sarcoid**

In 2014, the HRS published a consensus statement on the diagnosis and management of arrhythias associated with cardiac sarcoiditis, including recommendations for ICD implantation in patients with cardiac sarcoid (Table 14). The writing group concluded that although there are few data specific to ICD use in patients with cardiac sarcoid, data from the major primary and secondary prevention ICD trials were relevant to this population and recommendations from the general device guideline documents apply to this population.

**Table 14. Recommendations for ICD Implantation in Patients with Cardiac Sarcoid**

| **Recommendation** | **COR[1]** |
|---|---|
| ICD implantation **is recommended** in patients with cardiac sarcoid and one or more of the following:<br>• Spontaneous sustained ventricular arrhythmias, including prior cardiac arrest<br>• LVEF ≤35%, despite optimal medical therapy and a period of immunosuppression (if there is active inflammation). | I |
| ICD implantation **can be useful** in patients with cardiac sarcoid, independent of ventricular function, and one or more of the following:<br>• An indication for permanent pacemaker implantation;<br>• Unexplained syncope or near-syncope, felt to be arrhythmic in etiology;<br>• Inducible sustained ventricular arrhythmias (>30 seconds of monomorphic VT orpolymorphic VT) or clinically relevant VF.* | IIa |
| ICD implantation **may be considered** in patients with LVEF in the range of 36%–49% and/or an RV ejection fraction <40%, despite optimal medical therapy for heart failure and a period of immunosuppression (if there is active inflammation). | IIb |
| ICD implantation **is not recommended** in patients with no history of syncope, normal LVEF/RV ejection fraction, no LGE on CMR, a negative EP study, and no indication for permanent pacing. However, these patients should be closely followed for | III |

| | |
|---|---|
| deterioration in ventricular function. ICD implantation **is not recommended** in patients with one or more of the following:<br><br>• Incessant ventricular arrhythmias;<br>• Severe New York Heart Association class IV heart failure. | |

COR: Class of Recommendation; ICD: Implantable cardioverter defibrillator; LGE-CMR: late gadolinium-enhanced cardiovascular magnetic resonance; LOE: Level of Evidence; LVEF: left ventricular ejection fraction; RV: right ventricular.
[1]Class I: Strong; Class IIa: Moderate; Class IIb: Weak.

**Pediatric and Congenital Electrophysiology Society and Heart Rhythm Society**
The Pediatric and Congenital Electrophysiology Society and HRS (2014) issued an expert consensus statement on the recognition and management of arrhythmias in adult congenital heart disease. The statement made the following recommendations on the use of ICD therapy in adults with congenital heart disease (see Table 15).

**Table 15. Guidelines on the Management of CHD**

| Recommendation | COR | LOE |
|---|---|---|
| ICD therapy is indicated in adults with CHD who are survivors of cardiac arrest due to ventricular fibrillation or hemodynamically unstable ventricular tachycardia after evaluation to define the cause of the event and exclude any completely reversible etiology. | I | B |
| ICD therapy is indicated in adults with CHD and spontaneous sustained ventricular tachycardia who have undergone hemodynamic and electrophysiologic evaluation. | I | B |
| ICD therapy is indicated in adults with CHD and a systemic left ventricular ejection fraction <35%, biventricular physiology, and NYHA class II or III symptoms. | I | B |
| ICD therapy is reasonable in selected adults with tetralogy of Fallot and multiple risk factors for sudden cardiac death, such as left ventricular systolic or diastolic dysfunction, nonsustained ventricular tachycardia, QRS duration >180 ms, | IIa | B |

| | | |
|---|---|---|
| extensive right ventricular scarring, or inducible sustained ventricular tachycardia at electrophysiologic study. | | |
| ICD therapy may be reasonable in adults with a single or systemic right ventricular ejection fraction <35%, particularly in the presence of additional risk factors such as complex ventricular arrhythmias, unexplained syncope, NYHA functional class II or III symptoms, QRS duration >140 ms, or severe systemic AV valve regurgitation. | IIb | C |
| ICD therapy may be considered in adults with CHD and a systemic ventricular ejection fraction <35% in the absence of overt symptoms (NYHA class I) or other known risk factors. | Ib | C |
| ICD therapy may be considered in adults with CHD and syncope of unknown origin with hemodynamically significant sustained ventricular tachycardia or fibrillation inducible at electrophysiologic study. | Ib | B |
| ICD therapy may be considered for nonhospitalized adults with CHD awaiting heart transplantation. | Ib | C |
| ICD therapy may be considered for adults with syncope and moderate or complex CHD in whom there is a high clinical suspicion of ventricular arrhythmia and in whom thorough invasive and noninvasive investigations have failed to define a cause. | Ib | C |
| Adults with CHD and advanced pulmonary vascular disease (Eisenmenger syndrome) are generally not considered candidates for ICD therapy. | III[a] | |
| Endocardial leads are generally avoided in adults with CHD and intracardiac shunts. Risk assessment regarding hemodynamic circumstances, concomitant anticoagulation, shunt closure prior to endocardial lead placement, or alternative approaches for lead access should be individualized. | III[a] | |

AV: arteriovenous; CHD: coronary heart disease; COR: class of recommendation; ICD: implantable cardioverter defibrillator; LOE: level of evidence; NYHA: New York Heart Association.
[a] Not recommended.

Automatic Implantable Cardioverter Defibrillator (AICD)

Policy # 00008
Original Effective Date: 05/12/2003
Current Effective Date: 09/13/2021

**U.S. Preventive Services Task Force Recommendations**
Not applicable.

**Medicare National Coverage**
There is a National Coverage Determination for ICDs. According to the most recent publication (effective February 15, 2018), CMS will cover ICDs for the following patient indications:

1. Patients with a personal history of sustained VT or cardiac arrest due to Ventricular Fibrillation (VF).
2. Patients with a prior Myocardial Infarction (MI) and a measured Left Ventricular Ejection Fraction (LVEF) ≤ 0.30.
3. Patients who have severe ischemic dilated cardiomyopathy but no personal history of sustained VT or cardiac arrest due to VF, and have New York Heart Association (NYHA) Class II or III heart failure, LVEF≤ 35%.
4. Patients who have severe non-ischemic dilated cardiomyopathy but no personal history of cardiac arrest or sustained VT, NYHA Class II or III heart failure, LVEF ≤ 35%, and been on optimal medical therapy for at least three (3) months.
5. Patients with documented familial, or genetic disorders with a high risk of life-threatening tachyarrhytmias (sustained VT or VF), to include, but not limited to, long QT syndrome or hypertrophic cardiomyopathy.
6. Patients with an existing ICD may receive an ICD replacement if it is required due to the end of battery life, Elective Replacement Indicator (ERI), or device/lead malfunction.

For each group:

1. Patients must be clinically stable (e.g., not in shock, from any etiology);
2. LVEF must be measured by echocardiography, radionuclide (nuclear medicine) imaging, cardiac Magnetic Resonance Imaging (MRI), or catheter angiography;
3. Patients must not have:
    - Significant, irreversible brain damage; or,
    - Any disease, other than cardiac disease (e.g., cancer, renal failure, liver failure) associated with a likelihood of survival less than one (1) year; or,
    - Supraventricular tachycardia such as atrial fibrillation with a poorly controlled ventricular rate

**Ongoing and Unpublished Clinical Trials**
Some unpublished trials that may influence this review are listed in Table 16.

**Table 16. Summary of Key Trials**

| NCT No. | Trial Name | Planned Enrollment | Completion Date |
|---|---|---|---|
| *Ongoing* | | | |
| NCT02121158 | CSP #592 - Efficacy and Safety of ICD Implantation in the Elderly | 100 | Aug 2021 |
| NCT00673842[a] | Risk Estimation Following Infarction Noninvasive Evaluation - ICD Efficacy | 1000 | Dec 2021 |
| NCT02845531 | Implantable Cardioverter Defibrillator Versus Optimal Medical Therapy In Patients With Variant Angina Manifesting as Aborted Sudden Cardiac Death (VARIANT ICD) | 140 | Jun 2023 |
| NCT01296022[a] | Randomized Trial to Study the Efficacy and Adverse Effects of the Subcutaneous and Transvenous Implantable Cardioverter Defibrillator (ICD) in Patients With a Class I or IIa Indication for ICD Without an Indication for Pacing | 850 | Dec 2023 (extended followup) |
| NCT01736618[a] | Subcutaneous Implantable Cardioverter Defibrillator System Post Approval Study (UNTOUCHED) | 1766 | Oct 2021 |
| NCT02881255 | Avoid Transvenous Leads in Appropriate Subjects (Atlas) | 500 | Feb 2022 |
| NCT01085435[a] | Evaluation oF Factors Impacting Clinical Outcome and Cost Effectiveness of the S-ICD (The EFFORTLESS S-ICD Registry) | 994 | Dec 2023 |

| | | | |
|---|---|---|---|
| NCT02787785[a] | Multicenter Automatic Defibrillator Implantation Trial With Subcutaneous Implantable Cardioverter Defibrillator (MADIT S-ICD) | 40 | Dec 2023 |

NCT: national clinical trial.
[a] Denotes industry-sponsored or cosponsored trial.

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# Policy History

Original Effective Date: 05/12/2003
Current Effective Date: 09/13/2021
04/25/2003 Medical Policy Committee review

Policy # 00008
Original Effective Date: 05/12/2003
Current Effective Date: 09/13/2021

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|---|---|
| 05/12/2003 | Managed Care Advisory Council approval |
| 06/01/2004 | Medical Director review |
| 06/15/2004 | Medical Policy Committee review<br>Format revision.<br>No substance change to policy. |
| 06/28/2004 | Managed Care Advisory Council approval |
| 04/05/2005 | Medical Director review |
| 04/18/2005 | Medical Director review |
| 04/22/2005 | Medical Director review |
| 04/27/2005 | Medical Policy Committee approval. Investigational designation for specific clinical scenarios added. Clinical criteria revision. |
| 05/23/2005 | Managed Care Advisory Council approval |
| 05/03/2006 | Medical Director review<br>Format Revisions. Government regulations, literature updated; no change in policy statement. |
| 05/17/2006 | Medical Policy Committee review |
| 08/15/2007 | Medical Policy Committee review. Policy statement not medically necessary when patient selection criteria not met changed to investigational. Removed not medically necessary policy statement for selected conditions. |
| 12/12/2007 | Medical Director review |
| 12/19/2007 | Medical Policy Committee approval. No change to coverage eligibility. CMS added. FDA updated. |
| 12/03/2008 | Medical Director review |
| 12/17/2008 | Medical Policy Committee approval. Changed format and coverage by adopting BCBSA's. |
| 12/04/2009 | Medical Policy Committee approval |
| 12/16/2009 | Medical Policy Implementation Committee approval. Coverage eligibility unchanged. |
| 12/01/2010 | Medical Policy Committee approval |
| 12/15/2010 | Medical Policy Implementation Committee approval. Coverage eligibility unchanged. |
| 12/08/2011 | Medical Policy Committee review |
| 12/21/2011 | Medical Policy Implementation Committee approval. Policy statements specific to AICD indications in pediatric patients added to coverage section and Rationale. |

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| | Policy statement revised to clarify the indications in ischemic cardiomyopathy with separate indications for class II/III and class I patients. Policy statement with waiting time in nonischemic cardiomyopathy was revised. |
| 12/06/2012 | Medical Policy Committee review |
| 12/19/2012 | Medical Policy Implementation Committee approval. Added new investigational statement "Based on review of available data, the Company considers the use of a subcutaneous ICD investigational for all indications in adult and pediatric patients." |
| 02/04/2013 | Coding revised |
| 12/12/2013 | Medical Policy Committee review |
| 12/18/2013 | Medical Policy Implementation Committee approval. No change to coverage. |
| 12/04/2014 | Medical Policy Committee review |
| 12/17/2014 | Medical Policy Implementation Committee approval. A clause "…after reversible causes (e.g., acute ischemia) have been excluded" added to current statement on secondary prevention in adults. |
| 02/17/2015 | Coding update. |
| 08/03/2015 | Coding update: ICD10 Diagnosis code section added; ICD9 Procedure code section removed. |
| 12/03/2015 | Medical Policy Committee review |
| 12/16/2015 | Medical Policy Implementation Committee approval. New S-ICD section added to policy statements and added new bullet points to both Pediatric and Adult coverage statements. Statement added for Adults that ICD for secondary prevention in pts who do not meet criteria is considered INV. |
| 12/01/2016 | Medical Policy Committee review |
| 12/21/2016 | Medical Policy Implementation Committee approval. Coverage eligibility unchanged. |
| 01/01/2017 | Coding update: Removing ICD-9 Diagnosis Codes |
| 12/07/2017 | Medical Policy Committee review |
| 12/20/2017 | Medical Policy Implementation Committee approval. Coverage eligibility unchanged. |
| 12/06/2018 | Medical Policy Committee review |
| 12/19/2018 | Medical Policy Implementation Committee approval. Coverage eligibility unchanged. |
| 12/05/2019 | Medical Policy Committee review |

# Coding

*The five character codes included in the Blue Cross Blue Shield of Louisiana Medical Policy Coverage Guidelines are obtained from Current Procedural Terminology (CPT®)‡, copyright 2020 by the American Medical Association (AMA). CPT is developed by the AMA as a listing of descriptive terms and five character identifying codes and modifiers for reporting medical services and procedures performed by physician.*

*The responsibility for the content of Blue Cross Blue Shield of Louisiana Medical Policy Coverage Guidelines is with Blue Cross and Blue Shield of Louisiana and no endorsement by the AMA is intended or should be implied. The AMA disclaims responsibility for any consequences or liability attributable or related to any use, nonuse or interpretation of information contained in Blue Cross Blue Shield of Louisiana Medical Policy Coverage Guidelines. Fee schedules, relative value units, conversion factors and/or related components are not assigned by the AMA, are not part of CPT, and the AMA is not recommending their use. The AMA does not directly or indirectly practice medicine or dispense medical services. The AMA assumes no liability for data contained or not contained herein. Any use of CPT outside of Blue Cross Blue Shield of Louisiana Medical Policy*

Automatic Implantable Cardioverter Defibrillator (AICD)

Policy # 00008
Original Effective Date: 05/12/2003
Current Effective Date: 09/13/2021

*Coverage Guidelines should refer to the most current Current Procedural Terminology which contains the complete and most current listing of CPT codes and descriptive terms. Applicable FARS/DFARS apply.*

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Codes used to identify services associated with this policy may include (but may not be limited to) the following:

| Code Type | Code |
|---|---|
| CPT | 0614T, 33216, 33217, 33224, 33225, 33226, 33230, 33231, 33240, 33249, 33262, 33263, 33264, 33270, 33271 |
| HCPCS | C1721, C1722, C1777, C1824, C1882, C1895, C1896, C1899 |
| ICD-10 Diagnosis | D86.85, I42.0-I42.9, I46.2-I46.9, I47.0-I47.2, I49.01, I49.9, Q20.0-Q24.9 |

*Investigational – A medical treatment, procedure, drug, device, or biological product is Investigational if the effectiveness has not been clearly tested and it has not been incorporated into standard medical practice. Any determination we make that a medical treatment, procedure, drug, device, or biological product is Investigational will be based on a consideration of the following:

A. Whether the medical treatment, procedure, drug, device, or biological product can be lawfully marketed without approval of the U.S. Food and Drug Administration (FDA) and whether such approval has been granted at the time the medical treatment, procedure, drug, device, or biological product is sought to be furnished; or
B. Whether the medical treatment, procedure, drug, device, or biological product requires further studies or clinical trials to determine its maximum tolerated dose, toxicity, safety, effectiveness, or effectiveness as compared with the standard means of treatment or diagnosis, must improve health outcomes, according to the consensus of opinion among experts as shown by reliable evidence, including:
    1. Consultation with the Blue Cross and Blue Shield Association technology assessment program (TEC) or other nonaffiliated technology evaluation center(s);
    2. Credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community; or
    3. Reference to federal regulations.

**Medically Necessary (or "Medical Necessity") - Health care services, treatment, procedures, equipment, drugs, devices, items or supplies that a Provider, exercising prudent clinical judgment, would provide to a patient for the purpose of preventing, evaluating, diagnosing or treating an illness, injury, disease or its symptoms, and that are:

A. In accordance with nationally accepted standards of medical practice;
B. Clinically appropriate, in terms of type, frequency, extent, level of care, site and duration, and considered effective for the patient's illness, injury or disease; and
C. Not primarily for the personal comfort or convenience of the patient, physician or other health care provider, and not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of that patient's illness, injury or disease.

For these purposes, "nationally accepted standards of medical practice" means standards that are based on credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community, Physician Specialty Society recommendations and the views of Physicians practicing in relevant clinical areas and any other relevant factors.

‡ Indicated trademarks are the registered trademarks of their respective owners.

**NOTICE:** If the Patient's health insurance contract contains language that differs from the BCBSLA Medical Policy definition noted above, the definition in the health insurance contract will be relied upon for specific coverage determinations.

**NOTICE:** Medical Policies are scientific based opinions, provided solely for coverage and informational purposes. Medical Policies should not be construed to suggest that the Company recommends, advocates, requires, encourages, or discourages any particular treatment, procedure, or service, or any particular course of treatment, procedure, or service.