Automatic Implantable Cardioverter Defibrillator (AICD)

Policy # 00008
Original Effective Date: 05/12/2003
Current Effective Date: 08/12/2024

00055Applies 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 adult individuals to be **eligible for coverage.****

Primary Prevention
Patient Selection Criteria
Coverage eligibility for the use of an automatic implantable cardioverter defibrillator (AICD) in adult individuals will be considered when the following criteria are met:

- Ischemic cardiomyopathy when ANY of the following apply:
    - Left ventricular ejection fraction (LVEF) is ≤ 30% due to myocardial infarction ≥ 40 days previously in an individual with New York Heart Association functional (NYHA) functional class I symptoms when the response to optimal medical therapy has been adequately determined, and an individual is at least 90 days post revascularization (if revascularization has been performed); OR

  - LVEF is ≤ 35% due to myocardial infarction ≥ 40 days previously in an individual with NYHA functional class II or III symptoms when the response to optimal medical therapy has been adequately determined, and an individual is at least 90 days post revascularization (if revascularization has been performed); OR
  - LVEF is ≤ 40% due to prior myocardial infarction in an individual who has spontaneous nonsustained ventricular tachycardia AND positive electrophysiology study performed ≥ 96 hours following myocardial infarction; OR
- Nonischemic dilated cardiomyopathy and LVEF ≤ 35%, after reversible causes have been excluded, and the response to optimal medical therapy has been adequately determined; OR
- Hypertrophic cardiomyopathy when ANY of the following major risk factors for sudden cardiac death are present:
  - History of premature hypertrophic cardiomyopathy-related sudden death in 1 or more first-degree relatives younger than 50 years; OR
  - Left ventricular hypertrophy ≥ 30 mm; OR
  - One (1) or more runs of nonsustained ventricular tachycardia at heart rates of 120 beats per minute or greater on 24-hour Holter monitoring; OR
  - Prior unexplained syncope inconsistent with neurocardiogenic origin; OR
  - Judged to be at high risk for sudden cardiac death by a physician experienced in the care of individuals with hypertrophic cardiomyopathy (HCM); OR
- Spontaneous sustained ventricular tachycardia (VT persisting for at least 30 seconds or requiring termination due to hemodynamic compromise) in an individual with structural heart disease; OR
- 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; OR
- Diagnosis of cardiac sarcoid and considered to be at high risk for sudden cardiac death (see Policy Guidelines section).

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Secondary Prevention

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

- As a secondary prevention for individuals with a history of a life-threatening clinical event associated with ventricular arrhythmic events such as sustained ventricular tachyarrhythmia, after reversible causes (e.g., 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.

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

- Have had an acute myocardial infarction (i.e., less than 40 days before AICD treatment) and patient selection criteria are not met;
- Have NYHA functional class IV congestive heart failure (unless individual is eligible to receive a combination cardiac resynchronization therapy AICD device, OR is awaiting heart transplant or ventricular assist device;
- 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 AICD when patient selection criteria are not met to be **investigational.***

Based on review of available data, the Company considers use of the AICD for secondary prevention in individuals who do not meet the criteria for secondary prevention to be **investigational.***

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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 pediatric individuals who meet **ANY** of the following criteria to be **eligible for coverage**:**

- Survivors of cardiac arrest due to ventricular tachycardia or ventricular fibrillation, after reversible causes have been excluded; OR
- Long QT syndrome and ANY of the following:
    - Individuals who are survivors of sudden cardiac arrest (in combination with beta-blockers); OR
    - Individuals with syncope or ventricular tachycardia despite beta blocker (or in whom beta blockers are contraindicated); OR
    - Individuals who cannot take beta-blockers and for whom cardiac sympathetic denervation or other medications are not considered appropriate; OR
- Short QT syndrome in an individual who has a history of cardiac arrest or sustained ventricular tachycardia or fibrillation; OR
- Catecholaminergic polymorphic ventricular tachycardia and ANY of the following:
    - Individuals who are survivors of cardiac arrest; OR
    - Individuals who experience recurrent sustained ventricular tachycardia or recurrent syncope despite maximally tolerated beta blocker therapy (or in whom beta blockers are contraindicated), or cardiac sympathetic denervation; OR
- Brugada syndrome and ANY of the following:
    - Individuals who are survivors of sudden cardiac arrest; OR
    - Individuals who have documented spontaneous sustained ventricular tachycardia or fibrillation; OR
    - Individuals with history of syncope thought to be (or known to be) due to ventricular arrhythmia; OR

- Arrhythmogenic cardiomyopathy in individuals who are survivors of sudden cardiac arrest or sustained ventricular tachycardia that is not hemodynamically tolerated; OR
- Hypertrophic cardiomyopathy in individuals who are survivors of sudden cardiac arrest or have documented spontaneous sustained ventricular tachycardia; OR
- Nonischemic dilated cardiomyopathy in individuals who are survivors of sudden cardiac arrest or have documented spontaneous sustained ventricular tachycardia that is not due to completely reversible causes; OR
- Congenital heart disease in individuals who are survivors of sudden cardiac arrest, after reversible causes have been excluded; OR
- Symptomatic, sustained ventricular tachycardia in association with congenital heart disease in individuals who have undergone hemodynamic and electrophysiologic evaluation.

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 individuals 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 adult or pediatric individuals 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:

- Lack of adequate vascular access;
- Compelling reason to preserve existing vascular access (i.e., need for chronic dialysis; younger individual with anticipated long-term need for ICD therapy);
- Individual with endocarditis; OR
- 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.***

EXTRAVASCULAR IMPLANTABLE CARDIOVERTER DEFIBRILLATOR

Based on review of available data, the Company considers the use of the extravascular implantable cardioverter defibrillator (ICD) 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 the 2021 Pediatric and Congenital Electrophysiology Society and Heart Rhythm Society guidance on ICDs in children.

Criteria for Implantable Cardioverter Defibrillator Implantation in Individuals 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 individuals 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 individuals with inherited primary arrhythmia syndromes, 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):
  - Individuals with a diagnosis of LQTS who are survivors of cardiac arrest
  - Individuals with a diagnosis of LQTS who experience recurrent syncopal events while on β-blocker therapy.
- Brugada syndrome (BrS):
  - Individuals with a diagnosis of BrS who are survivors of cardiac arrest
  - Individuals with a diagnosis of BrS who have documented spontaneous sustained ventricular tachycardia (VT) with or without syncope
  - Individuals 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)
  - Individuals with a diagnosis of BrS who develop ventricular fibrillation during programmed electrical stimulation.
- Catecholaminergic polymorphic ventricular tachycardia (CPVT):
  - Individuals with a diagnosis of CPVT who are survivors of cardiac arrest
  - Individuals 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):

- Individuals with a diagnosis of SQTS who are survivors of cardiac arrest
- Individuals with a diagnosis of SQTS who are symptomatic and have documented spontaneous VT with or without syncope
- Individuals with a diagnosis of SQTS or are asymptomatic or symptomatic and have a family history of sudden cardiac death.

NOTE: For congenital LQTS, individuals 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 individuals with a family history of sudden cardiac death due to LQTS, infants with a diagnosis of LQTS with functional 2:1 atrioventricular block, individuals with a diagnosis of LQTS in conjunction with a diagnosis of Jervell and Lange-Nielsen syndrome or Timothy syndrome, and individuals 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 Individuals With Cardiac Sarcoid

Criteria for ICD placement in individuals with cardiac sarcoid derive from a 2014 consensus statement from the HRS and 2017 joint guidelines from the AHA, ACC, and HRS.

Indications for consideration of ICD placement in individuals 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.

Subcutaneous ICD
There are no defined guidelines for the selection of S-ICD versus T-ICD. Currently, S-ICDs are generally considered in the following situations:

- Individuals at high risk of infection, inadequate venous access, and any patient without a pacing indication
- Younger individuals (e.g., age less than 45 years) due to the expected longevity of the implanted leads and a desire to avoid chronic transvenous leads (e.g., individuals with hypertrophic cardiomyopathy, congenital cardiomyopathies, or inherited channelopathies)
- Individuals at high risk for bacteremia, such as individuals on hemodialysis or with chronic indwelling endovascular catheters.
- Individuals with challenging vascular access or prior complications with T-ICDs.

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 (LVEF) and prior myocardial infarction (MI); nonischemic dilated cardiomyopathy with reduced LVEF; hypertrophic cardiomyopathy and additional risk factors; congenital heart disease, particularly with recurrent syncope; and cardiac ion channelopathies.

Treatment
Implantable cardioverter defibrillators (ICDs) monitor a patient's heart rate, recognize ventricular fibrillation 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 individuals who have experienced a potentially life-threatening episode of VT (near SCD); and (2) primary prevention, ie, use in individuals 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 (PMA) process. The FDA labeled indications generally include individuals 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 individuals with previous MI and reduced ejection 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 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.

In April 2021, Medtronic issued a recall of the Evera, Viva, Brava, Claria, Amplia, Compia, and Visia ICDs and cardiac resynchronization therapy defibrillators (CRT-Ds) due to an unexpected and rapid decrease in battery life. The decrease in battery life is caused by a short circuit and will cause some devices to produce a "Recommended Replacement Time" warning earlier than expected. Some devices may progress from this warning to full battery depletion within as little as 1 day. The device may stop functioning if the user does not respond to the first warning. In August 2022, Medtronic issued a recall of the Cobalt XT, Cobalt, and Crome ICDs and CRT-Ds because of risk that the

devices may issue a short circuit alert and deliver a reduced energy electric shock instead of delivering a second phase of high voltage therapy. The reduced energy electrical shock may fail to correct an arrhythmia or may cause an irregular heartbeat. In July 2023, Medtronic issued a recall of the Cobalt XT, Cobalt, Crome, Visia AF, Visia AF MRI, Evera, Evera MRI, Prio, MRI, and Mirro MRI devices (along with some CRT-D devices) due to the potential for a reduced energy shock due to inappropriate activation of the short circuit protection feature. The FDA identified all 3 of these events as Class I recalls, the most serious type of recall, indicating a situation in which use of these devices may cause serious injuries or death.

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 (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. The 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.

Extravascular Implantable Cardioverter Defibrillators
In 2023, the Aurora EV-ICD™‡ MRI SureScan device was approved by the FDA for patients who are at risk of life-threatening ventricular arrhythmias and have not had a prior sternotomy and do not need pacing. This was the first extravascular ICD to be approved in the United States. Extravascular ICD leads are placed in the anterior mediastinum rather than inside the heart or veins.

Table 1. Implantable Cardioverter Defibrillators with Food and Drug Administration 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
Extravascular		
Aurora EV-ICD	Medtronic	Oct 2023

PMA: premarket application.

Rationale/Source

This medical policy was developed through consideration of peer-reviewed medical literature generally recognized by the relevant medical community, U.S. Food and Drug Administration approval status, nationally accepted standards of medical practice and accepted standards of medical

practice in this community, technology evaluation centers, reference to federal regulations, other plan medical policies, and accredited national guidelines.

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

Summary of Evidence

Transvenous Implantable Cardioverter Defibrillators

For individuals who have a high risk of sudden cardiac death (SCD) due to ischemic or nonischemic cardiomyopathy in adulthood who receive transvenous implantable cardioverter defibrillator (T-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. Randomized controlled trials assessing early implantable cardioverter defibrillator (ICD) use following recent myocardial infarction (MI) did not support a benefit for immediate versus delayed implantation for at least 40 days. For nonischemic cardiomyopathy (NICM), there are less clinical trial data, but pooled estimates of available evidence from RCTs enrolling patients with NICM 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 an improvement in the net health outcome.

For individuals who have a high risk of SCD due to hypertrophic cardiomyopathy (HCM) in adulthood who receive T-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 studies are considered adequate evidence to support the use of T-ICDs in patients with HCM. The evidence is sufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have a high risk of SCD due to an inherited cardiac ion channelopathy who receive T-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 studies are considered adequate evidence to support the use of T-ICDs in patients with inherited cardiac ion channelopathy. The evidence is sufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have a high risk of SCD due to cardiac sarcoid who receive T-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 sarcoidosis), 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 T-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 an improvement in the net health outcome.

For individuals who have had symptomatic life-threatening sustained ventricular tachycardia (VT) or ventricular fibrillation (VF) or who have been resuscitated from sudden cardiac arrest (secondary prevention) who receive T-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 an improvement in the net health outcome.

Subcutaneous Implantable Cardioverter Defibrillators
For individuals who need an ICD and have a contraindication to a T-ICD but no indications for antibradycardia pacing and no antitachycardia pacing-responsive arrhythmias who receive subcutaneous ICD (S-ICD) placement, the evidence includes an RCT, nonrandomized studies, and case series. Relevant outcomes are OS, morbid events, quality of life, and treatment-related mortality and morbidity. An RCT found that S-ICD significantly decreases the risk of lead-related perioperative complications compared to T-ICD. However, this study was not powered to detect differences in the rates of failed shocks or inappropriate shocks and an extension study is ongoing. Nonrandomized controlled studies have reported success rates in terminating laboratory-induced VF that are similar to T-ICD. Case series have reported high rates of detection and successful conversion of VF, and inappropriate shock rates in the range reported for T-ICD. Given the need for ICD placement in this population at risk for SCD, with the assumption that appropriate shocks are life-saving, these studies are considered adequate evidence to support the use of S-ICDs in patients with contraindication to T-ICD. The evidence is sufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who need an ICD and have no indications for antibradycardia pacing or antitachycardia pacing-responsive arrhythmias with 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 Prospective, Randomized Comparison of Subcutaneous and Transvenous Implantable Cardioverter Defibrillator Therapy (PRAETORIAN) 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 [HR], 0.99; 95% confidence interval [CI], 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 2 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.

Extravascular Implantable Cardioverter Defibrillators
For individuals who need an ICD who receive an extravascular ICD (E-ICD), the evidence includes nonrandomized studies. Relevant outcomes are OS, morbid events, quality of life, and treatment-related mortality and morbidity. The largest available study with an E-ICD reported high rates of defibrillation after implantation and a low rate of major complications, with a numerically similar rate of inappropriate shocks compared to studies with T-ICD and S-ICD. The major limitation of the study is the lack of an active control group. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

Additional Information
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 implantable cardioverter defibrillator (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 ICD (S-ICD). 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 S-ICD 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 9 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 time frames 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 et al - Heart Failure (2022)
In 2022, the American Heart Association (AHA), American College of Cardiology (ACC), and the Heart Failure Society of America released a guideline for the management of heart failure. This guideline includes ICD recommendations which are summarized in Table 2.

Table 2. Guideline for the Management of Heart Failure - Recommendations for Implantable Cardioverter Defibrillators

Recommendation	COR	LOE
"In patients with nonischemic DCM or ischemic heart disease at least 40 days post-MI with LVEF ≤35% and NYHA class I or II symptoms on chronic GDMT, who have reasonable expectation of meaningful survival for >1 year, ICD therapy is recommended for primary prevention of SCD to reduce total mortality."	1	A
"A transvenous ICD provides high economic value in the primary prevention of SCD particularly when the patient's risk of death caused by ventricular arrhythmia 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."		A
"In patients at least 40 days post-MI with LVEF ≤30% and NYHA class I symptoms while receiving GDMT, who have reasonable expectation of meaningful survival for >1 year, ICD therapy is recommended for primary prevention of SCD to reduce total mortality."	1	B-R
"In patients with genetic arrhythmogenic cardiomyopathy with high-risk features of sudden death, with EF ≤45%, implantation of ICD is reasonable to decrease sudden death."	2a	B-NR
"For patients whose comorbidities or frailty limit survival with good functional capacity to <1 year, ICD and CRT-D are not indicated."	No benefit	C-LD

A: high; B-NR: moderate, non-randomized; B-R: moderate, randomized; C-LD: limited data; COR: class of recommendation; CRT-D: cardiac resynchronization therapy with defibrillation; DCM: dilated cardiomyopathy; EF: ejection fraction; GDMT: guideline-directed management and therapy; ICD: implantable cardioverter defibrillator: LOE: level of evidence; LVEF: left ventricular ejection fraction; MI: myocardial infarction; NYHA: New York Heart Association; SCD: sudden cardiac death.

American Heart Association/American College of Cardiology et al - Hypertrophic Cardiomyopathy (2020)

In 2020, the AHA and ACC published a joint Guideline for the Diagnosis and Treatment of Patients with Hypertrophic Cardiomyopathy. Recommendations relevant to this review are summarized in Table 3.

Table 3. Patient Selection for Implantable Cardioverter Defibrillator 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 the 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 HCM 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 preferences, lifestyle, and expected potential need for pacing for bradycardia or ventricular tachycardia termination.	I	B-NR

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

American Heart Association/American College of Cardiology et al - Ventricular Arrhythmias and Prevention of Sudden Cardiac Death (2017)

The AHA, ACC, and Heart Rhythm Society (2017) published joint guidelines on the management of patients with ventricular arrhythmias and the prevention of sudden cardiac death. This guideline supersedes the 2008 guideline for device-based therapy of cardiac rhythm abnormalities and the subsequent 2012 focused update. The most up-to-date recommendations on the use of T-ICD devices from the 2017 guidelines are presented in Tables 4 to 8. Table 9 summarizes the most up-to-date recommendations regarding S-ICDs.

Table 4. Recommendations on Use of Implantable Cardioverter Defibrillators as Secondary Prevention of Sudden Cardiac Death of Ischemic Heart Disease or Nonischemic Cardiomyopathy

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 sustained VT (LOE: B-NR) not due to reversible causes, an ICD is recommended if meaningful survival of greater than 1 year is expected."	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, an ICD is recommended if meaningful survival of greater than 1 year is expected.""	I	B-NR
"In patients resuscitated from SCA due to coronary artery spasm in whom medical therapy is ineffective or not tolerated, an ICD is reasonable if meaningful survival of greater than 1 year is expected.""	IIa	B-NR
"In patients resuscitated from SCA due to coronary artery spasm, an ICD in addition to medical therapy may be reasonable if meaningful survival of greater than 1 year is expected.""	IIb	B-NR

"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, an ICD is recommended if meaningful survival of greater than 1 year is expected."	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 if meaningful survival of greater than 1 year is expected."	IIa	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%), an ICD is recommended if meaningful survival of greater than 1 year is expected."	I	B-NR
"In patients with arrhythmogenic right ventricular cardiomyopathy and syncope presumed due to VA, an ICD can be useful if meaningful survival of greater than 1 year is expected.""	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; NICM: nonischemic cardiomyopathy; RVEF: right ventricular ejection fraction; SCA: sudden cardiac arrest; SCD: sudden cardiac death; VA: ventricular arrhythmia; VF: ventricular fibrillation; VT: ventricular tachycardia.

Table 5. Recommendations on Use of Implantable Cardioverter Defibrillators as a Primary Prevention of Ischemic Heart Disease or Nonischemic Cardiomyopathy

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, an ICD is recommended if meaningful survival of greater than 1 year is expected."	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	I	A

NYHA class I HF despite GDMT, an ICD is recommended if meaningful survival of greater than 1 year is expected."		
"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, an ICD is recommended if meaningful survival of greater than 1 year is expected."	I	B-R
"In nonhospitalized patients with NYHA class IV symptoms who are candidates for cardiac transplantation or an LVAD, an ICD is reasonable if meaningful survival of greater than 1 year is expected."	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
"In patients with NICM, HF with NYHA class II-III symptoms and an LVEF of 35% or less, despite GDMT, an ICD is recommended if meaningful survival of greater than 1 year is expected."	I	A
"In patients with NICM due to a *Lamic A/C* mutation who have 2 or more risk factors (NSVT, LVEF <45%, nonmissense mutation, and male sex), an ICD can be beneficial if meaningful survival of greater than 1 year is expected."	IIa	B-NR
"In patients with NICM, HF with NYHA class I symptoms and an LVEF of 35% or less, despite GDMT, an ICD may be considered if meaningful survival of greater than 1 year is expected."	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 expert opinion; CRT: cardiac resynchronization therapy; COR: class of recommendation; 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; MI: myocardial infarction; NICM: nonischemic cardiomyopathy; 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 6. Recommendations on Use of Implantable Cardioverter Defibrillators for Hypertrophic Cardiomyopathy

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, an ICD is recommended if meaningful survival of greater than 1 year is expected"	I	B-NR
"In patients with HCM and 1 or more of the following risk factors, an ICD is reasonable if meaningful survival of greater than 1 year is expected: • Maximum LV wall thickness ≥30 mm (LOE: B-NR). • SCD in 1 or more first-degree relatives presumably caused by HCM (LOE: C-LD). • 1 or more episodes of unexplained syncope within the preceding 6 months (LOE: C-LD)"	IIa	B-NR 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 an ICD is reasonable if meaningful survival of greater than 1 year is expected"	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 7. Recommendations on Use of Implantable Cardioverter Defibrillators for Cardiac Sarcoidosis

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 8. Recommendations on Use of Implantable Cardioverter Defibrillators 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, an ICD may be reasonable if meaningful survival of greater than 1 year is expected."	IIb	B-NR
"In patients with neuromuscular disorders, primary and secondary prevention ICDs are recommended for the same indications as for patients with NICM if meaningful survival of greater than 1 year is expected"	I	B-NR
"In patients with Emery-Dreifuss and limb-girdle type IB muscular dystrophies with progressive cardiac involvement, an ICD is reasonable if meaningful survival of greater than 1 year is expected."	IIa	B-NR
"In patients with myotonic dystrophy type 1 with an indication for a permanent pacemaker, an ICD may be considered to minimize the risk of SCA from VT if meaningful survival of greater than 1 year is expected."	IIb	B-NR
"In patients with a cardiac channelopathy and SCA, an ICD is recommended if meaningful survival of greater than 1 year is expected."	I	B-NR
"In high-risk patients with symptomatic long QT syndrome in whom a beta blocker is ineffective or not tolerated, intensification of therapy with additional medications (guided by consideration of the particular long QT syndrome type), left cardiac sympathetic denervation, and/or an ICD is recommended."	I	B-NR
"In patients with catecholaminergic polymorphic VT and recurrent sustained VT or syncope, while receiving adequate or maximally tolerated beta blocker,	I	B-NR

treatment intensification with either combination medication therapy, left cardiac sympathetic denervation, and/or an ICD is recommended."		
"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, an ICD is recommended if meaningful survival of greater than 1 year is expected."	I	B-NR
"In patients with early repolarization pattern on ECG and cardiac arrest or sustained VA, an ICD is recommended if meaningful survival of greater than 1 year is expected."	I	B-NR
"In patients with short QT syndrome who have a cardiac arrest or sustained VA, an ICD is recommended if meaningful survival greater than 1 year is expected."	I	B-NR
"In patients resuscitated from SCA due to idiopathic polymorphic VT or VF, an ICD is recommended if meaningful survival of greater than 1 year is expected."	I	B-NR
"For older patients and those with significant comorbidities, who meet indications for a primary prevention ICD, an ICD is reasonable if meaningful survival of greater than 1 year is expected."	IIa	B-NR
"In patients with adult congenital heart disease with SCA due to VT or VF in the absence of reversible causes, an ICD is recommended if meaningful survival of greater than 1 year is expected."	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 if meaningful survival of greater than 1 year is expected."	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 9. Recommendations on Use of Subcutaneous Implantable Cardioverter Defibrillators

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; COR: class of recommendation; CRT: cardiac resynchronization therapy; ICD: implantable cardioverter defibrillator; LOE: level of evidence; VT: ventricular tachycardia.
[a] Harm.

American Heart Association - Cardiomyopathy in Children (2023)
In 2023, the AHA published a scientific statement on cardiomyopathy in children. The statement recommends a discussion of benefit and risk, including the potential for sudden death and ICD discharges. The criteria for ICD implementation in children are the same as in adults after pediatric-specific risks are taken into account.

Heart Rhythm Society et al - Position Paper (2022)
The Heart Rhythm Society, in conjunction with the European Heart Rhythm Association and the Asia Pacific Heart Rhythm Society published a position paper on several cardiac devices, including S-ICDs. The authors reviewed the available literature and provided practical considerations for appropriate use. There was strong consensus that T-ICDs should be considered in all patients with an indication for preventing sudden cardiac death, and that non-T-ICDs can be considered in patients who do not require active pacing or who require a non-transvenous approach. There was general agreement that a T-ICD or leadless pacemaker could be added to a non-T-ICD if the patient develops

a need for cardiac pacing. The position paper mentioned extravascular ICDs but did not provide any formal recommendations regarding their use due to a lack of available data.

Heart Rhythm Society- Arrhythmogenic Cardiomyopathy (2019)
In 2019, the Heart Rhythm Society 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 10.

Table 10. Recommendations on Risk Stratification and Implantable Cardioverter Defibrillator 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 (2013)

The Heart Rhythm Society, 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 (Table 11).

Table 11. Recommendations on Implantable Cardioverter Defibrillators in 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: • Are survivors of a cardiac arrest and/or • Have documented spontaneous sustained VT with or without syncope.	I
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 stand alone 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/or have 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; HRS: Heart Rhythm Society; 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.

Heart Rhythm Society - Cardiac Sarcoidosis (2014)
In 2014, the Heart Rhythm Society published a consensus statement on the diagnosis and management of arrhythmias associated with cardiac sarcoidosis, including recommendations for ICD implantation in patients with cardiac sarcoidosis (Table 12). The writing group concluded that although there are few data specific to ICD use in patients with cardiac sarcoidosis, 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 12. Recommendations for Implantable Cardioverter Defibrillator Implantation in Patients with Cardiac Sarcoidosis

Recommendation	**COR[1]**
ICD implantation **is recommended** in patients with cardiac sarcoidosis and one or more of the following: • Spontaneous sustained ventricular arrhythmias, including prior cardiac arrest • 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 sarcoidosis, independent of ventricular function, and one or more of the following: • An indication for permanent pacemaker implantation; • Unexplained syncope or near-syncope, felt to be arrhythmic in etiology; • Inducible sustained ventricular arrhythmias (>30 seconds of monomorphic VT or polymorphic 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 deterioration in ventricular function. ICD implantation **is not recommended** in patients with one or more of the following: • Incessant ventricular arrhythmias; • Severe New York Heart Association class IV heart failure.	III

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

Pediatric and Congenital Electrophysiology Society et al

The Pediatric and Congenital Electrophysiology Society and Heart Rhythm Society (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 (Table 13).

Table 13. Recommendations on Implantable Cardioverter Defibrillators in the Management of Congenital Heart Disease

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, extensive right ventricular scarring, or inducible sustained ventricular tachycardia at electrophysiologic study.	IIa	B
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	III[a]	

anticoagulation, shunt closure prior to endocardial lead placement, or alternative approaches for lead access should be individualized.		

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

In 2021, the Pediatric and Congenital Electrophysiology Society and Heart Rhythm Society also issued an expert consensus statement on the indications and management of cardiovascular implantable electronic devices in pediatric patients. Table 14 summarizes recommendations for ICD therapy from this statement.

Table 14. Recommendations for Implantable Cardioverter Defibrillator Therapy in Pediatric Patients

Recommendation	COR	LOE
ICD implantation is indicated for survivors of SCA due to VT/VF if completely reversible causes have been excluded and an ICD is considered to be more beneficial than alternative treatments that may significantly reduce the risk of SCA.	I	B-NR
ICD implantation may be considered for patients with sustained VT that cannot be adequately controlled with medication and/or catheter ablation.	2b	C-EO
ICD therapy may be considered for primary prevention of SCD in patients with genetic cardiovascular diseases and risk factors for SCA or pathogenic mutations and family history of recurrent SCA.	2b	C-EO
ICD therapy is not indicated for patients with incessant ventricular tachyarrhythmias due to risk of ICD storm.	3: Harm	C-EO
ICD therapy is not indicated for patients with ventricular arrhythmias that are adequately treated with medication and/or catheter ablation.	3: Harm	C-LD

ICD therapy is not indicated for patients who have an expected survival <1 year, even if they meet ICD implantation criteria specified in the above recommendations.	3: Harm	C-EO
ICD implantation along with the use of beta-blockade is indicated for patients with a diagnosis of LQTS who are survivors of SCA.	I	B-NR
ICD implantation is indicated in LQTS patients with symptoms in whom beta-blockade is either ineffective or not tolerated and cardiac sympathetic denervation or other medications are not considered effective alternatives.	I	B-NR
ICD therapy may be considered for primary prevention in LQTS patients with established clinical risk factors and/or pathogenic mutations.	2b	C-LD
ICD implantation is not indicated in asymptomatic LQTS patients who are deemed to be at low risk of SCA and have not been tried on beta-blocker therapy.	3: Harm	C-LD
ICD implantation is indicated in patients with a diagnosis of CPVT who experience cardiac arrest of arrhythmic syncope despite maximally tolerated beta-blocker plus flecainide and/or cardiac sympathetic denervation.	I	C-LD
ICD implantation is reasonable in combination with pharmacologic therapy with or without cardiac sympathetic denervation when aborted SCA is the initial presentation of CPVT. Pharmacologic therapy and/or cardiac sympathetic denervation without ICD may be considered as an alternative.	2a	C-LD
ICD therapy may be considered in CPVT patients with polymorphic/bidirectional VT despite optimal pharmacologic therapy with or without cardiac sympathetic denervation.	2b	C-LD
ICD implantation is not indicated in asymptomatic patients with a diagnosis of CPVT.	3: Harm	C-EO
ICD implantation is indicated in patients with a diagnosis of BrS who are survivors of SCA or have documented spontaneous sustained VT.	I	B-NR

ICD implantation is reasonable for patients with BrS with a spontaneous type I Brugada ECG pattern and recent syncope presumed due to ventricular arrhythmias.	2a	B-NR
ICD implantation may be considered in patients with syncope presumed due to ventricular arrhythmias with a type I Brugada ECG pattern only with provocative medications.	2b	C-EO
ICD implantation is not indicated in asymptomatic BrS patients in the absence of risk factors.	3: No benefit	C-EO
ICD implantation is indicated in patients with HCM who are survivors of SCA or have spontaneous sustained VT.	I	B-NR
For children with HCM who have ≥1 primary risk factors, including unexplained syncope, massive left ventricular hypertrophy, nonsustained VT, or family history of early HCM-related SCD, ICD placement is reasonable after considering the potential complications of long-term ICD placement.	2a	B-NR
ICD implantation may be considered in patients with HCM without the above risk factors but with secondary risk factors for SCA such as extensive LGE cardiac MRI or systolic dysfunction.	2b	B-NR
ICD implantation is not indicated in patients with an identified HCM genotype in the absence of known pediatric SCA risk factors.	3: Harm	C-LD
ICD implantation is indicated in patients with ACM who have been resuscitated from SCA or sustained VT that is not hemodynamically tolerated.	I	B-NR
ICD implantation is reasonable in patients with ACM with hemodynamically tolerated sustained VT, syncope presumed due to ventricular arrhythmia, or an LVEF ≤35%.	2a	B-NR
ICD implantation may be considered in patients with inherited ACM associated with increased risk of SCD based on an assessment of additional risk factors.	2b	C-LD
ICD implantation is indicated in patients with NIDCM who either survive SCA or experience sustained VT not due to completely reversible causes.	I	B-NR

ICD implantation may be considered in patients with NIDCM and syncope or an LVEF ≤35%, despite optimal medical therapy.	2b	C-LD
ICD implantation is not recommended in patients with medication-refractory advanced heart failure who are not cardiac transplantation or left ventricular assist device candidates.	3: Harm	C-EO
ICD therapy is not indicated for patients with advanced heart failure who are urgently listed for cardiac transplantation and will remain in the hospital until transplantation, even if they meet ICD implantation criteria specified in the above recommendations.	3: No benefit	C-EO
ICD implantation is indicated for CHD patients who are survivors of SCA after evaluation to define the cause of the event and exclude any completely reversible causes.	I	B-NR
ICD implantation is indicated for CHD patients with hemodynamically unstable sustained VT who have undergone hemodynamics and EP evaluation.	I	C-LD
ICD implantation is reasonable for CHD patients with systemic LVEF <35% and sustained VT or presumed arrhythmogenic syncope.	2a	C-LD
ICD implantation may be considered for CHD patients with spontaneous hemodynamically stable sustained VT who have undergone hemodynamic and EP evaluation.	2b	C-EO
ICD implantation may be considered for CHD patients with unexplained syncope in the presence of ventricular dysfunction, nonsustained VT, or inducible ventricular arrhythmias at EP study.	2b	C-LD
ICD implantation may be considered for CHD patients with a single or systemic right ventricular ejection fraction ≤35%, particularly in the presence of additional risk factors such as VT, arrhythmic syncope, or severe systemic AV valve insufficiency.	2b	C-EO

ACM: arrhythmogenic cardiomyopathy; AV: atrioventricular; B-NR: moderate, non-randomized; BrS: Brugada syndrome; C-EO: consensus of expert opinion; CHD: congenital heart disease; C-LD: limited data; COR: class of recommendation; CPVT: catecholaminergic polymorphic ventricular

tachycardia; ECG: electrocardiogram; EP: electrophysiology; HCM: hypertrophic cardiomyopathy; ICD: implantable cardioverter defibrillator; LGE: late gadolinium-enhanced; LOE: level of evidence; LQTS: long QT syndrome; LVEF: left ventricular ejection fraction; MRI: magnetic resonance imaging; NIDCM: non-ischemic dilated cardiomyopathy; SCA: sudden cardiac arrest; SCD: sudden cardiac death; VF: ventricular fibrillation; VT: ventricular tachycardia.

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), Centers for Medicare and Medicaid Services will cover ICDs for the following patient indications:

1. Patients with a personal history of sustained ventricular tachycardia (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 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 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 15.

Table 15. Summary of Key Trials

NCT No.	Trial Name	Planned Enrollment	Completion Date
Ongoing			
NCT02845531	Implantable Cardioverter Defibrillator Versus Optimal Medical Therapy In Patients With Variant Angina Manifesting as Aborted Sudden Cardiac Death (VARIANT ICD)	140	Jun 2030
NCT00673842[a]	Risk Estimation Following Infarction Noninvasive Evaluation - ICD Efficacy	700	Dec 2024
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 follow-up)
Unpublished			
NCT01085435[a]	Evaluation of Factors Impacting Clinical Outcome and Cost Effectiveness of the S-ICD (The EFFORTLESS S-ICD Registry)	994	Jan 2024

NCT02787785[a]	Multicenter Automatic Defibrillator Implantation Trial With Subcutaneous Implantable Cardioverter Defibrillator (MADIT S-ICD)	40	Oct 2023
NCT01736618[a]	Subcutaneous Implantable Cardioverter Defibrillator System Post Approval Study (UNTOUCHED)	1766	Oct 2021

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: 08/12/2024

04/25/2003	Medical Policy Committee review
05/12/2003	Managed Care Advisory Council approval
06/01/2004	Medical Director review
06/15/2004	Medical Policy Committee review Format revision. 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 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.
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. 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
12/11/2019	Medical Policy Implementation Committee approval. Coverage eligibility unchanged. Coding update
03/09/2020	Coding update
05/11/2020	Coding update
06/10/2020	Coding update
07/02/2020	Medical Policy Committee review
07/08/2020	Medical Policy Implementation Committee approval. Indication for cardiac sarcoid added. Implantable cardioverter defibrillator (ICD) is eligible for coverage for patients with cardiac sarcoid with conditions.
08/05/2021	Medical Policy Committee review
08/11/2021	Medical Policy Implementation Committee approval." 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" added to coverage criteria for primary prevention.
10/01/2021	Verbiage updated and coding section adjusted.
03/16/2022	Coding update

08/04/2022 Medical Policy Committee review
08/10/2022 Medical Policy Implementation Committee approval. No change to coverage. Added statement to policy guideline section.
08/03/2023 Medical Policy Committee review
08/09/2023 Medical Policy Implementation Committee approval. No change to coverage.
07/02/2024 Medical Policy Committee review
07/10/2024 Medical Policy Implementation Committee approval. Added "LVEF is < 40% due to prior myocardial infarction in an individual who has spontaneous nonsustained ventricular tachycardia AND positive electrophysiology study performed > 96 hours following myocardial infarction" to Primary prevention criteria. Added when patient selection criteria are not met as investigational denial. Pediatric criteria totally updated. Added "Individual with endocarditis: as investigational under pediatric section. Added " Based on review of available data, the Company considers the use of the extravascular implantable cardioverter defibrillator (ICD) to be investigational."

Next Scheduled Review Date: 07/2025

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 2023 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: 08/12/2024

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.

CPT is a registered trademark of the American Medical Association.

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

Code Type	Code
CPT	33216, 33217, 33230, 33231, 33240, 33249, 33262, 33263, 33264, 33270, 33271 Delete codes effective 08/01/2024: 0614T, 33224, 33225, 33226
HCPCS	C1721, C1722, C1777, C1882, C1895, C1896, C1899, G0448
ICD-10 Diagnosis	All related Diagnoses

*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 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.

NOTICE: Federal and State law, as well as contract language, including definitions and specific contract provisions/exclusions, take precedence over Medical Policy and must be considered first in determining eligibility for coverage.