MEDICAL POLICY

POLICY TITLE	CARDIOVERTER-DEFIBRILLATORS (IMPLANTABLE AND EXTERNAL)
POLICY NUMBER	MP- 1.081

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I. POLICY

Implantable Defibrillator-Adults

The use of the automatic implantable cardioverter defibrillator (ICD) may be considered **medically necessary** in adults who meet the following criteria:

Primary Prevention:

- Ischemic cardiomyopathy with New York Heart Association (NYHA) functional class II or class III symptoms, a history of myocardial infarction at least 40 days before ICD treatment, and left ventricular ejection fraction of 35% or less; **or**
- Ischemic cardiomyopathy with NYHA functional class I symptoms, a history of myocardial infarction at least 40 days before ICD treatment, and left ventricular ejection fraction of 30% or less; **or**
- Nonischemic dilated cardiomyopathy and left ventricular ejection fraction of 35% or less, after reversible causes have been excluded, and the response to optimal medical therapy has been adequately determined; **or**
- Hypertrophic cardiomyopathy (HCM) with 1 or more major risk factors for sudden cardiac death:
    - history of premature HCM-related sudden death in 1 or more first-degree relatives younger than 50 years;
    - left ventricular hypertrophy greater than 30 mm;
    - 1 or more runs of 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;
    - an abnormal blood pressure response to treadmill exercise in the setting of one of the following clinical modifiers: (a) >30mmHg LVOT gradient at rest; (b) late gadolinium enhancement on MRI; or (c) evidence of apical scarring; **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; **or**
    - Brugada syndrome; **or**
    - short QT syndrome; **or**
    - catecholaminergic polymorphic ventricular tachycardia.

- Diagnosis of any one of the following cardiomyopathic conditions and considered to be at high risk for sudden cardiac death:
    - Arrhythmogenic Right Ventricular Dysplasia/Cardiomyopathy
    - Sarcoidosis
    - Giant Cell Myocarditis
    - Chagas Disease

Secondary Prevention:

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

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

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

The use of the ICD for secondary prevention is considered **investigational** for patients who do not meet the criteria for secondary prevention. There is insufficient evidence to support a conclusion concerning the health outcomes or benefits associated with this procedure for the above indications.

Implantable Defibrillator-Pediatrics

The use of the ICD may be considered **medically necessary** in children who meet ANY of the following criteria:

- Survivors of cardiac arrest, after reversible causes have been excluded; **or**
- Symptomatic, sustained ventricular tachycardia in association with congenital heart disease in patients who have undergone hemodynamic and electrophysiologic evaluation; **or**

- Congenital heart disease with recurrent syncope of undetermined origin in the presence of either ventricular dysfunction or inducible ventricular arrhythmias.
- HCM with 1 or more major risk factors for sudden cardiac death:
    - history of premature HCM-related sudden death in 1 or more first-degree relatives younger than 50 years;
    - left ventricular hypertrophy greater than 30 mm;
    - 1 or more runs of 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;
    - an abnormal blood pressure response to treadmill exercise in the setting of one of the following clinical modifiers: (a) >30mmHg LVOT gradient at rest; (b) late gadolinium enhancement on MRI; or (c) evidence of apical scarring; **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; **or**
    - Brugada syndrome; **or**
    - short QT syndrome; **or**
    - catecholaminergic polymorphic ventricular tachycardia.
- Diagnosis of any one of the following cardiomyopathic conditions and considered to be at high risk for sudden cardiac death:
    - Arrhythogenic Right Ventricular Dysplasia/Cardiomyopathy
    - Sarcoidosis
    - Giant Cell Myocarditits
    - Chagas Disease

The use of the ICD is considered **investigational** for all other indications in pediatric patients as there is insufficient evidence to support a conclusion concerning the health outcomes or benefits associated with this procedure.

Subcutaneous ICD (S-ICD®)

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

- Have a contraindication to a transvenous ICD due to one or more of the following: (1) lack of adequate vascular access; (2) compelling reason to preserve existing vascular access (i.e., need for chronic dialysis; younger patient with anticipated long-term need for ICD therapy); or (3) history of need for explantation of a transvenous ICD due to a complication, with ongoing need for ICD therapy.

- Have no indication for antibradycardia pacing; **and**
- Do not have ventricular arrhythmias that are known or anticipated to respond to antitachycardia pacing.

The use of a subcutaneous ICD is considered **investigational** for individuals who do not meet the criteria outlined above. There is insufficient evidence to support a conclusion concerning the health outcomes or benefits associated with this procedure for any other indications.

POLICY GUIDELINES

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

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

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

Criteria for ICD implantation in patients with cardiac ion channelopathies are derived 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 implantation for each cardiac ion channelopathy are as follows:

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

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.

Wearable Cardioverter Defibrillators (WCD)

Use of an FDA approved wearable cardioverter defibrillator (WCD) may be considered medically necessary for a period of up to three (3) months when the following criteria are met:

1. At least eight (8) years of age or older; **and**
2. The device will be worn at least 22 hours per day (greater than 90% wear time); **and** the patient meets one of the following criteria:

   - Requires the WCD as interim treatment for those who meet the criteria for an implantable cardioverter-defibrillator; **or**
   - A documented episode of ventricular fibrillation or a sustained (lasting 30 seconds or longer) ventricular tachyarrhythmia. These dysrhythmias may be either spontaneous or induced during an electrophysiologic (EP) study, but may not be due to a transient or

reversible cause and not occur during the first 48 hours of an acute myocardial infarction; **or**

- A previously implanted defibrillator now requires explantation; **or**
- As a bridge to left ventricular (LV) improvement for **one** of the following indications:

    - LV ejection fraction (EF) less than or equal to 35% after cardiac events such as:
        - After recent acute myocardial infarction (MI) during the 40-day period under which ICD implantation is not indicated or deferred, Reevaluation of LVEF should occur no later than three (3) months after a MI. If LVEF remains 35% or less, an implantable cardioverter is indicated; **or**
        - Coronary revascularization procedures such as before and after coronary artery bypass graft (CABG) or percutaneous coronary intervention (PCI) during the 90-day ICD waiting period; **or**
        - Recently diagnosed non-ischemic cardiomyopathy during the three (3)-month to nine (9)-month period awaiting LV improvement or ICD implantation.
    - Heart transplantation; **or**
    - As an alternative to an ICD in an individual who has a documented contraindication to an ICD (e.g., systemic infection, lack of vascular access).

WCD for any other indications will be considered **not medically necessary**.

Automatic External Defibrillators (AED)

Automatic external defibrillators (AED) for home use are considered **investigational**, as there is insufficient evidence to support a conclusion concerning the health outcomes or benefits associated with this procedure.

Cross-references:

MP-2.007 Biventricular Pacemakers (Cardiac Resynchronization Therapy) for the Treatment of Heart Failure
MP-2.057 T-Wave Alternans Testing
MP-2.233 Genetic Testing for Cardiac Ion Channelopathies

II. PRODUCT VARIATIONS

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This policy is applicable to all programs and products administered by Capital BlueCross unless otherwise indicated below.

FEP PPO- Refer to FEP Medical Policy Manual MP- 2.02.15, Wearable Cardioverter Defibrillators, and MP- 7.01.44, Implantable Cardioverter Defibrillator. The FEP Medical Policy

Manual can be found at: https://www.fepblue.org/benefit-plans/medical-policies-and-utilization-management-guidelines/medical-policies

III. DESCRIPTION/BACKGROUND

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Implantable Cardioverter Defibrillator

Ventricular Arrhythmia and Sudden Cardiac Death

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

Treatment

Implantable cardioverter defibrillators (ICDs) monitor a patient's heart rate, recognize ventricular fibrillation (VF) or ventricular tachycardia (VT), and deliver an electric shock to terminate these arrhythmias to reduce the risk of SCD. Indications for ICD placement can be broadly subdivided into (1) secondary prevention, i.e., use in patients who have experienced a potentially life-threatening episode of VT (near SCD); and (2) primary prevention, i.e., use in patients who are considered at high risk for SCD but who have not yet experienced life-threatening VT or VF.

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

A subcutaneous implantable cardioverter defibrillator (S-ICD) has been developed. It does not use transvenous leads and thus avoids the need for venous access and complications associated with the insertion of venous leads. Rather, the S-ICD uses a subcutaneous electrode implanted adjacent to the left sternum. The electrodes sense the cardiac rhythm and deliver countershocks through the subcutaneous tissue of the chest wall.

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

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REGULATORY STATUS

Transvenous Implantable Cardioverter Defibrillators

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

Subcutaneous ICDs

In September 2012, the Subcutaneous Implantable Defibrillator (S-ICD™) System was approved by FDA through the PMA process for the treatment of life-threatening ventricular tachyarrhythmias in patients who do not have symptomatic bradycardia, incessant ventricular tachycardia, or spontaneous, frequently recurring ventricular tachycardia 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 FDA through the PMA supplement process.

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 (St. Paul, MN)	Jul 1993
Current® Plus ICD (originally: Cadence Tiered Therapy Defibrillation System)	St. Jude Medical (St. Paul, MN)	Jul 1993
Dynagen™, Inogen™, Origen™, and Teligen® Family (originally: Ventak, Vitality, Cofient family)	Boston Scientific (Marlborough, MA)	Jan 1998
Evera™ Family (originally: Virtuosos/Entrust/Maximo/ Intrisic/Marquis family)	Medtronic (Minneapolis, MN)	Dec 1998
Subcutaneous		
Subcutaneous Implantable Defibrillator System (S-ICD™)	Cameron Health (San Clemente, CA); 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 policy addresses ICDs alone, when used solely to treat patients at risk for ventricular arrhythmias.

External Cardioverter-Defibrillators (Wearable and Automatic External Defibrillator [AED]

The wearable cardioverter defibrillator is an external device intended to perform the same tasks as an ICD, without invasive procedures. It is primarily intended for temporary conditions for which an implantable device is contraindicated, or for the period during which the need for a

permanent implantable device is uncertain. It consists of a vest worn continuously underneath the patient's clothing. Part of this vest is the "electrode belt" that contains the cardiac-monitoring electrodes and the therapy electrodes that deliver a counter shock. The vest is connected to a monitor with a battery pack and alarm module worn on the patient's belt. The monitor contains the electronics that interpret the cardiac rhythm and determines when a counter shock is necessary. The alarm module alerts the patient to certain conditions by lights or voice messages, during which time a conscious patient can abort or delay the shock.

An automatic external defibrillator (AED) is a portable compact device, which detects and treats cardiac arrest related to cardiac arrhythmias, VF, and VT. All AEDs, which have been approved for use in the U.S., utilize a synthesized voice that prompts users through each step. The use of AEDS is taught in Basic Life Support (BLS) classes and units are designed for non-medical operators.

The American Heart Association (AHA) supports the placement of AEDs in targeted public places (e.g. office complexes, shopping malls, sports complexes, etc.); however, the literature to date has not demonstrated an improved survival rate for home AED placement.

REGULATORY STATUS

In December 2001, the Lifecor WCD® 2000 system was approved by the U.S. Food and Drug Administration (FDA) through the premarket approval process for "adult patients who are at risk for cardiac arrest and are either not candidates for or refuse an implantable defibrillator." The vest was renamed the Zoll® LifeVest®.

In 2015, FDA approved the LifeVest® "for certain children who are at risk for sudden cardiac arrest, but are not candidates for an implantable defibrillator due to certain medical conditions or lack of parental consent."

FDA product code: MVK.

IV. RATIONALE

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IMPLANTABLE CARDIOVERTER DEFIBRILLATOR

Summary of Evidence

Transvenous ICDs

For individuals who have a high risk of SCD due to ischemic or to nonischemic cardiomyopathy in adulthood who receive TV-ICD placement for primary prevention, the evidence includes multiple well-designed and well-conducted RCTs as well as systematic reviews of these trials. Relevant outcomes are overall survival, morbid events, quality of life, and treatment-related mortality and morbidity. Multiple, well-done RCTs have shown a benefit in overall mortality for patients with ischemic cardiomyopathy and reduced ejection fraction. RCTs assessing early ICD use following recent myocardial infarction did not support a benefit for immediate vs delayed

implantation for at least 40 days. For nonischemic cardiomyopathy, there is less clinical trial data, but pooled estimates of available evidence from RCTs enrolling patients with nonischemic cardiomyopathy and from subgroup analyses of RCTs with mixed populations have supported a survival benefit for this group. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

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

For individuals who have a high risk of SCD due to an inherited cardiac ion channelopathy who receive TV-ICD placement for primary prevention, the evidence includes small cohort studies of patients with these conditions treated with ICDs. Relevant outcomes are overall survival, morbid events, quality of life, and treatment-related mortality and morbidity. The limited evidence for patients with long QT syndrome, catecholaminergic polymorphic ventricular tachycardia, and Brugada syndrome has reported high rates of appropriate shocks. No studies were identified on the use of ICDs for patients with short QT syndrome. Studies comparing outcomes between patients treated and untreated with ICDs are not available. However, given the relatively small patient populations with these channelopathies and the high risk of cardiac arrhythmias, clinical trials are unlikely. Given the long-term high risk of SCD in patients with inherited cardiac ion channelopathy, with the assumption that appropriate shocks are life-saving, these rates are considered adequate evidence to support the use of TV-ICDs in patients with inherited cardiac ion channelopathy. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

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

Subcutaneous ICDs

For individuals who need an ICD and have a contraindication to a TV-ICD but no indications for antibradycardia pacing and no antitachycardia pacing–responsive arrhythmias who receive S-ICD placement, the evidence includes nonrandomized studies and case series. Relevant

outcomes are overall survival, morbid events, quality of life, and treatment-related mortality and morbidity. Nonrandomized controlled studies have reported success rates in terminating laboratory-induced VF that are similar to TV-ICD. Case series have reported high rates of detection and successful conversion of VF, and inappropriate shock rates in the range reported for TV-ICD. Given the need for ICD placement in this population at risk for SCD, with the assumption that appropriate shocks are life-saving, these rates are considered adequate evidence to support the use of S-ICDs in patients with contraindication to TV-ICD. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

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

WEARABLE CARDIAC DEFIBRILLATOR

Summary of Evidence

Temporary Contraindications

For individuals who have a temporary contraindication to an ICD who receive a WCD, the evidence includes prospective cohort studies. Relevant outcomes are overall survival, morbid events, functional outcomes, and treatment-related morbidity. A small number of patients meet established criteria for an ICD but have a transient contraindication for an implantable device, most commonly an infectious process. The available data have established that the WCD device can detect lethal arrhythmias and can successfully deliver a countershock in most cases. In patients scheduled for ICD placement, the WCD will improve outcomes as an interim treatment. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

Immediate Post Myocardial Infarction

For individuals who are in the immediate post myocardial infarction period who receive a WCD, the evidence includes RCTs and a technology assessment that assess ICD devices, given the absence of evidence on WCD devices. Relevant outcomes are overall survival, morbid events,

functional outcomes, and treatment-related morbidity. Two RCTs have reported that overall survival did not improve after treatment with a permanent ICD. While both trials reported a decrease in sudden cardiac death, there was a corresponding increase in non–sudden cardiac death events, resulting in no net survival benefit. Analysis of data from a retrospective postmarket registry with WCD reported a success rate of 82% but interpretation of registry data is limited in absence of a control group. Given the lack of evidence that a permanent ICD improves outcomes in the immediate post myocardial infarction period, a WCD would not be expected to improve outcomes. The evidence is insufficient to determine the effects of the technology on health outcomes.

Other High-Risk Conditions
For individuals who are post coronary artery bypass graft surgery and are at high risk for lethal arrhythmias, awaiting heart transplantation and at high risk for lethal arrhythmias, have newly diagnosed nonischemic cardiomyopathy, or have peripartum cardiomyopathy who receive a WCD, the evidence includes an RCT evaluating early ICD placement after coronary artery bypass graft, and case series and registry data for other indications that assess ICD devices, given the absence of evidence on WCD devices. Relevant outcomes are overall survival, morbid events, functional outcomes, and treatment-related morbidity. For high-risk post coronary artery bypass graft patients, an RCT reported no difference in overall survival associated with early ICD placement. For other indications, there are no RCTs that demonstrate benefit of an ICD placement. Because of absence of any benefit of ICD and lack of any RCTs to demonstrate benefit of a WCD, the evidence does not currently permit conclusions that a WCD will improve patient outcomes. The evidence is insufficient to determine the effects of the technology on health outcomes.

V. DEFINITIONS

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CARDIAC ARREST is the sudden cessation of functional circulation (pulselessness).

CARDIOMYOPATHY is any disease that affects the heart muscle, diminishing cardiac performance.

FIRST-DEGREE RELATIVE refers to a parent, sibling or child.

NEW YORK HEART ASSOCIATION CLASS I refers to patients with cardiac disease but without resulting limitation of physical activity. Ordinary physical activity does not cause undue fatigue, palpitation, dyspnea or anginal pain.

NEW YORK HEART ASSOCIATION CLASS II REFERS to patients with cardiac disease resulting in slight limitation of physical activity. They are comfortable at rest. Ordinary physical activity results in fatigue, palpitation, dyspnea or anginal pain.

NEW YORK HEART ASSOCIATION CLASS III refers to patients with cardiac disease which results in marked limitation of physical activity. These patients are comfortable at rest. Less than ordinary activity causes fatigue, palpitation, dyspnea, or anginal pain.

NEW YORK HEART ASSOCIATION CLASS IV refers to patients with cardiac disease which results in the inability to carry out any physical activity without discomfort. Symptoms of heart failure or the anginal syndrome may be present even at rest. If any physical activity is undertaken, discomfort is increased.

QT INTERVAL is the period from the beginning for the QRS complex to the end of the T wave on the electrocardiogram (EKG). It reflects the refractory period of the heart. A long Q-T interval is associated with life-threatening ventricular tachycardia.

TACHYARRHYTHMIA is any cardiac rhythm disturbance in which the heart rate exceeds one hundred (100) beats per minute.

TACHYCARDIA is an abnormally rapid heart rate, greater than one hundred (100) beats per minute in an adult.

VENTRICULAR FIBRILLATION is a treatable, but potentially lethal dysrhythmia present in nearly half of all cases of cardiac arrest. It is marked on the electrocardiogram by rapid, chaotic nonrepetitive waveforms; and clinically by the absence of effective circulation of the blood (pulselessness).

VENTRICULAR TACHYCARDIA is three or more consecutive ventricular ectopic complexes occurring at a rate of one hundred (100) to two hundred fifty (250) beats per minute.

VI. BENEFIT VARIATIONS

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The existence of this medical policy does not mean that this service is a covered benefit under the member's contract. Benefit determinations should be based in all cases on the applicable contract language. Medical policies do not constitute a description of benefits. A member's individual or group customer benefits govern which services are covered, which are excluded, and which are subject to benefit limits and which require preauthorization. Members and providers should consult the member's benefit information or contact Capital BlueCross for benefit information.

VII. DISCLAIMER

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Capital BlueCross's medical policies are developed to assist in administering a member's benefits, do not constitute medical advice and are subject to change. Treating providers are solely responsible for medical advice and treatment of members. Members should discuss any medical policy related to their coverage or condition with their provider and consult their benefit information to determine if the service is covered. If there is a discrepancy

between this medical policy and a member's benefit information, the benefit information will govern. Capital BlueCross considers the information contained in this medical policy to be proprietary and it may only be disseminated as permitted by law.

VIII. CODING INFORMATION

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Note: This list of codes may not be all-inclusive, and codes are subject to change at any time. The identification of a code in this section does not denote coverage as coverage is determined by the terms of member benefit information. In addition, not all covered services are eligible for separate reimbursement.

Covered when medically necessary:

CPT Codes®								
33216	33217	33218	33220	33223	33230	33226	33231	33240
33241	33243	33244	33249	33262	33263	33264	33270	33271
33273	93644	93745						

HCPCS Codes	Description
C1721	Cardioverter-defibrillator, dual chamber (implantable)
C1722	Cardioverter-defibrillator, single chamber (implantable)
C1777	Lead, cardioverter-defibrillator, endocardial single coil (implantable)
C1882	Cardioverter-defibrillator, other than single or dual chamber (implantable)
C1895	Lead, cardioverter-defibrillator, endocardial dual coil (implantable)
C1896	Lead, cardioverter-defibrillator, other than endocardial single or dual coil (implantable)
E0617	External defibrillator with integrated electrocardiogram analysis
K0606	Automatic external defibrillator, with integrated electrocardiogram analysis, garment type

ICD-10 CM Diagnosis Codes	Description
B57.0	Acute Chagas' disease with heart involvement
B57.2	Chagas' disease (chronic) with heart involvement
D86.85	Sarcoid myocarditis
I25.5	Ischemic cardiomyopathy
I40.1	Isolated myocarditis
I42.0	Dilated cardiomyopathy

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ICD-10 CM Diagnosis Codes	Description
I42.1	Obstructive hypertrophic cardiomyopathy
I42.2	Other hypertrophic cardiomyopathy
I42.8	Other cardiomyopathies
I45.81	Long QT syndrome
I46.2	Cardiac arrest due to underlying cardiac condition
I46.8	Cardiac arrest due to other underlying condition
I46.9	Cardiac arrest, cause unspecified
147.1	Supraventricular tachycardia
I47.2	Ventricular tachycardia
I49.01	Ventricular fibrillation
I51.7	Cardiomegaly
Q24.8	Other specified congenital malformations of heart
R55	Syncope and collapse
Z86.74	Personal history of sudden cardiac arrest

IX. REFERENCES

TOP

Implantable Cardioverter Defibrillator

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Wearable Cardioverter-Defibrillators

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X. POLICY HISTORY

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MP 1.081	**CAC 9/28/04**
	CAC 5/31/05
	CAC 4/25/06
	CAC 3/27/07
	CAC 5/27/08
	CAC 11/25/08
	CAC 9/29/09 Consensus Review
	CAC 9/28/10 Consensus review.
	CAC 10/25/11 Minor Review due to BCBSA policy revision. Added medical necessity and investigational statements for implantable defibrillators for pediatric indications. Revised medical necessity criteria for implantable defibrillators for Primary Prevention. Adopted Medicare criteria for external wearable defibrillators. Clarified investigational statement for AEDs with addition of "home use".
	Admin Change 3/5/12 Deleted "interim treatment" from statement related to wearable external defibrillator.
	CAC 3 /26/13 Minor Policy statement added regarding the use of subcutaneous ICD which is considered investigational for all indications. Changed FEP variation to reference FEP Medical Policy Manual MP-2.02.15 Wearable Cardioverter Defibrillators as a Bridge to ICD Placement and MP- 7.01.44 Implantable Cardioverter Defibrillator.
	05/15/2013-Administrative code review. New investigational indications added.
	1/28/14 Consensus. No change to policy statements, references updated. Partial BCBSA.
	01/05/15- New 2015 codes added to policy.
	CAC 3/24/15 Minor revision. BCBSA criteria for both wearable cardioverter-defibrillators and implantable cardioverter defibrillators are being adopted and replacing current policy criteria to include: **Implantable:**

To be addressed by reviewer, removal of these three indications to match BCBSA indications: o High-risk patients with Brugada Syndrome; or o High-risk patients with arrhythmogenic right ventricular dysplasia; or o Long QT syndrome for patients on concurrent beta blocker therapy still experiencing syncope and/or VT while receiving beta blockers and who have reasonable expectation of survival with a good functional status for more than 1 year; or **Wearable:** **Adopt the following indications to match BCBSA:** Use of WCDs for the prevention of sudden cardiac death is considered medically necessary as interim treatment for those who: • meet the criteria for an implantable cardioverter-defibrillator (in policy above); and • have a temporary contraindication to receiving an ICD, such as a systemic infection, at the current time; and • have been scheduled for an ICD placement or who had an ICD removed and have been rescheduled for placement of another ICD once the contraindication is treated. Use of WCDs for the prevention of sudden cardiac death is considered investigational for the following indications when they are the sole indication for a wearable cardioverter-defibrillator: • Patients in the immediate (i.e., less than 40 days) period following an acute myocardial infarction. • Patients post-CABG [coronary artery bypass graft] surgery • Patients with newly diagnosed nonischemic cardiomyopathy • Women with peripartum cardiomyopathy • High-risk patients awaiting heart transplant All other indications are considered investigational. References and rationale updated. There is a Medicare variation on the policy. Policy coded.
11/2/15 Administrative change. LCD number changed from L13613 to L33690 due to NHIC update to ICD-10.

CAC 5/31/16 Minor revision. The following changes were made to the Implantable Cardioverter-Defibrillator.
For adult ICD implantation for primary prevention, an additional risk factor was added for those with hypertrophic cardiomyopathy who demonstrate an abnormal blood pressure response to treadmill exercise in the setting of one of the following clinical modifiers: (a) >30mmHg LVOT gradient at rest; (b) late gadolinium enhancement on MRI; or (c) evidence of apical scarring.
In addition for adult ICD implantation for primary prevention, the diagnosis of any one of the following cardiomyopathic conditions considered to be at high risk for sudden cardiac death were added to include the following:

- Arrythmogenic Right Ventricular Dysplasia/Cardiomyopathy
- Sarcoidosis
- Giant Cell Myocarditis
- Chagas Disease

For pediatric ICD:
Indications revised as follows:

- Hypertrophic cardiomyopathy (HCM) with 1 or more major risk factors for sudden cardiac death:
  - history of premature HCM-related sudden death in 1 or more first-degree relatives younger than 50 years
  - left ventricular hypertrophy greater than 30 mm
  - 1 or more runs of 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
  - an abnormal blood pressure response to treadmill exercise in the setting of one of the following clinical modifiers: (a) >30mmHg LVOT gradient at rest; (b) late gadolinium enhancement on MRI; or (c) evidence of apical scarring 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 were added+:

- congenital long QT syndrome; OR
- Brugada syndrome; OR
- short QT syndrome; OR
- catecholaminergic polymorphic ventricular tachycardia.

	Diagnosis of any one of the following cardiomyopathic conditions considered to be at high risk for sudden cardiac death were added to include the following: o Arrhythogenic Right Ventricular Dysplasia/Cardiomyopathy o Sarcoidosis o Giant Cell Myocarditits o Chagas Disease The use of a subcutaneous ICD may be considered **medically necessary** for adults or children who have an indication for ICD implantation for primary or secondary prevention for any of the above reasons and meet all of the following criteria: • Have a contraindication to a transvenous ICD due to one or more of the following: (1) lack of adequate vascular access; (2) compelling reason to preserve existing vascular access (i.e., need for chronic dialysis; younger patient with anticipated long-term need for ICD therapy); or (3) history of need for explantation of a transvenous ICD due to a complication, with ongoing need for ICD therapy. • Have no indication for antibradycardia pacing; AND • Do not have ventricular arrhythmias that are known or anticipated to respond to antitachycardia pacing. The use of a subcutaneous ICD is considered investigational for individuals who do not meet the criteria outlined above. Also added the ICD is considered investigational for secondary prevention in patients who do not meet medical necessity criteria for secondary prevention. References and rationale updated**.** Policy guidelines added. Coding reviewed.
	Admin update 1/1/17: Product variation section reformatted.
	1/1/18 Admin Update: Medicare variations removed from Commercial Policies.
	CAC 11/28/17 Minor revision. WCDs: revised medically necessary criteria. Description/Background, Rationale and Reference sections updated. Coding reviewed.
	7/17/18 Consensus review. No changes to the policy statements. References updated. Rationale revised.

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