MEDICAL POLICY

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

Effective Date:	12/1/2023

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 III symptoms, a history of myocardial infarction (MI) at least 40 days before ICD treatment, and left ventricular ejection fraction (LVEF) 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 **one or more** major risk factors for sudden cardiac death listed below:
  - History of premature HCM-related sudden death in 1 or more first-degree relatives younger than 50 years; **or**
  - Left ventricular hypertrophy greater than 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 HCM; **OR**
- Diagnosis of any one of the following cardiac ions channelopathies and considered to be at high risk for sudden cardiac death (see Policy Guidelines):
  - Congenital long QT syndrome (LQTS) with **either** of the following:
    - Diagnosis of LQTS and survivor of cardiac arrest; **or**
    - Diagnosis of LQTS with recurrent syncopal events while on beta-blocker therapy; **OR**

- Brugada syndrome (BrS) with **at least one** of the following:
  - Diagnosis of BrS and survivors of cardiac arrest; **or**
  - Diagnosis of BrS with documented spontaneous sustained ventricular tachycardia (VT) with or without syncope; **or**
  - Spontaneous diagnostic type 1 electrocardiogram (ECG) with history of syncope, seizure, or nocturnal agonal respiration judged to be likely caused by ventricular arrhythmias (after noncardiac causes have been ruled out); **or**
  - Diagnosis of BrS and develop ventricular fibrillation (VF) during programmed electrical stimulation; **OR**
- Short QT syndrome (SQTS) with **at least one** of the following:
  - Diagnosis of SQTS and survivor of cardiac arrest; **or**
  - Diagnosis of SQTS, symptomatic with documented spontaneous VT with or without syncope; **or**
  - Diagnosis of SQTS, asymptomatic or symptomatic with a family history of sudden cardiac death; **OR**
- Catecholaminergic polymorphic ventricular tachycardia (CPVT) with **either** of the following:
  - Diagnosis of CPVT and survivor of cardiac arrest; **or**
  - Diagnosis of CPVT with recurrent syncope or polymorphic/bidirectional ventricular tachycardia (VT) despite optimal medical management, and/or left cardiac sympathetic denervation

- Diagnosed with cardiac sarcoid and considered to be at high risk for sudden cardiac death with **at least one** of the following:
  - Spontaneous sustained ventricular arrhythmias, including prior cardiac arrest, if meaningful survival of greater than 1 year is expected; **or**
  - 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; **or**
  - 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 orpolymorphic VT) or clinically relevant VF; **or**
  - An indication for permanent pacemaker implantation; **OR**.
- Any **one** of the following cardiomyopathic conditions and considered to be at high risk for sudden cardiac death:
  - arrhythmogenic Right Ventricular Dysplasia/Cardiomyopathy

- Giant Cell Myocarditis
- Chagas Disease

Secondary Prevention*:*

- 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.

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

- Have had an acute myocardial infarction (i.e., less than 40 days before ICD treatment);
- Have NYHA Class IV congestive heart failure (unless individual 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 individuals who do not meet the criteria for secondary prevention. There is insufficient evidence to support a general 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 individuals 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; **OR**
- HCM with **one** 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; **or**
  - Massive (often defined as 30 mm or higher) left ventricular hypertrophy based on age-specific norms; **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 HCM; **OR**

- Diagnosis of any one of the following cardiac ions channelopathies and considered to be at high risk for sudden cardiac death (see Policy Guidelines):
  - Congenital long QT syndrome (LQTS) with **either** of the following:
    - Diagnosis of LQTS and survivor of cardiac arrest; **or**
    - Diagnosis of LQTS with recurrent syncopal events while on beta-blocker therapy; **OR**
  - Brugada syndrome (BrS) with **at least one** of the following:
    - Diagnosis of BrS and survivors of cardiac arrest; **or**
    - Diagnosis of BrS with documented spontaneous sustained ventricular tachycardia (VT) with or without syncope; **or**
    - Spontaneous diagnostic type 1 electrocardiogram (ECG) with history of syncope, seizure, or nocturnal agonal respiration judged to be likely caused by ventricular arrhythmias (after noncardiac causes have been ruled out); **or**
    - Diagnosis of BrS and develop ventricular fibrillation (VF) during programmed electrical stimulation; **OR**
  - Short QT syndrome (SQTS) with **at least one** of the following:
    - Diagnosis of SQTS and survivor of cardiac arrest; **or**
    - Diagnosis of SQTS, symptomatic with documented spontaneous VT with or without syncope; **or**
    - Diagnosis of SQTS, asymptomatic or symptomatic with a family history of sudden cardiac death; **OR**
  - Catecholaminergic polymorphic ventricular tachycardia (CPVT) with **either** of the following:
    - Diagnosis of CPVT and survivor of cardiac arrest; **or**
    - Diagnosis of CPVT with recurrent syncope or polymorphic/bidirectional ventricular tachycardia (VT) despite optimal medical management, and/or left cardiac sympathetic denervation

The use of the ICD is considered **investigational** for all other indications in pediatric individuals as there is insufficient evidence to support a general 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 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); or

    - 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 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 general conclusion concerning the health outcomes or benefits associated with this procedure for any other indications.

Implantable cardioverter-defibrillator system with substernal electrode(s)

Insertion of implantable cardioverter-defibrillator systems with substernal electrode is considered **not medically necessary** as there is insufficient evidence to support a conclusion concerning the health outcomes or benefits associated with this procedure for the above indications.

Wearable Cardioverter Defibrillators (WCD)

Use of an FDA approved wearable cardioverter defibrillator (WCD) for the prevention of sudden cardiac death may be considered medically necessary for those who meet the criteria for an implantable cardioverter-defibrillator and the following criteria are met:

- As an alternative to an ICD in a individual who has a documented contraindication to an ICD (e.g., systemic infection, lack of vascular access); **OR**
- A previously implanted defibrillator now requires explantation; **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**
- LVEF less than or equal to 35% after cardiac events such as:
    - 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 coronary artery bypass graft (CABG) or percutaneous coronary intervention (PCI) within the last 90 days; **or**
    - Recently diagnosed non-ischemic cardiomyopathy during the three (3)-month period awaiting LV improvement or ICD implantation.
- Awaiting heart transplantation and considered high risk for arrhythmia; **OR**
- Familial or inherited conditions with a high risk of life-threatening VT such as long QT syndrome or hypertrophic cardiomyopathy
- Decline ICD placement

WCD for any other indications are 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 general conclusion concerning the health outcomes or benefits associated with this procedure.

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

It is uncommon for individuals to have a temporary contraindication to implantable cardioverter defibrillator (ICD) placement. The most common reason will be a systemic infection that requires treatment before the ICD can be implanted. The wearable cardioverter defibrillator (WCD) should only be used short-term while the temporary contraindication (e.g., systemic infection) is being clinically managed. Once treatment is completed, the permanent ICD should be implanted.

Criteria for ICD 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.

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 Patients With Cardiac Sarcoid
Criteria for ICD placement in individuals with cardiac sarcoid derive from a 2014 consensus statement from the Heart Rhythm Society (HRS) and 2017 joint guidelines from the AHA, ACC, and HRS.

Cross-references:
MP 2.007 Cardiac Interventions in 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 only applicable to certain programs and products administered by Capital Blue Cross and subject to benefit variations as discussed in Section VI. Please see additional information below.

FEP PPO - Refer to FEP Medical Policy Manual. 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

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.

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 (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 ventricular fibrillation 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. Also, devices typically have approval in the secondary prevention setting for patients with a previous myocardial infarction and reduced injection fraction.

REGULATORY STATUS

Transvenous Implantable Cardioverter Defibrillators

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

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

Table 1. Implantable Cardioverter Defibrillators with FDA Approval

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

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]

A wearable cardioverter defibrillator (WCD) is a temporary, external device that is an alternative to an implantable cardioverter defibrillator (ICD). 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.

Sudden Cardiac Arrest
Sudden cardiac arrest (SCA) is the most common cause of death in patients with coronary artery disease.

Treatment
The implantable cardioverter defibrillator (ICD) has proven effective in reducing mortality for survivors of SCA and for patients with documented malignant ventricular arrhythmias. More recently, use of ICDs has been broadened by studies reporting a reduction in mortality for patients at risk for ventricular arrhythmias, such as patients with prior myocardial infarction (MI) and reduced ejection fraction (EF).

Implantable cardioverter defibrillators consist of implantable leads, which are placed percutaneously in the heart, that are connected to a pulse generator placed beneath the skin of the chest or abdomen. Placement of the ICD is a minor surgical procedure. Potential adverse events of ICD placement are bleeding, infection, pneumothorax, and delivery of unnecessary counter shocks.

The wearable cardioverter defibrillator (WCD) is an external device intended to perform the same tasks as an ICD, without invasive procedures. 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.

U.S. Food and Drug Administration (FDA) labeled indications for the WCD are adults at risk for SCA who either are not candidates for or refuse an implantable ICD. Some experts have suggested that the indications for a WCD should be broadened to include other populations at high-risk for SCA. The potential indications include:

- Bridge to transplantation (i.e., the Use of a Wearable Defibrillator in Terminating Tachyarrhythmias in Patients at High Risk for Sudden Death [WEARIT] study population)
- Bridge to implantable device or clinical improvement (i.e., the Patients at High Risk for Sudden Death after a Myocardial Infarction or Bypass Surgery not receiving an ICD for up to four months [BIROAD] study population)
    - Post bypass with EF less than 30%
    - Post bypass with ventricular arrhythmias or syncope within 48 hours of surgery
    - Post MI with EF less than 30%
    - Post MI with ventricular arrhythmias within 48 hours

- Drug-related arrhythmias (during drug washout or after, during evaluation of long-term risk)
- Patients awaiting revascularization
- Patients too ill to undergo device implantation
- Patients who refuse device therapy.

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 2001, the Lifecor WCD® 2000 system was approved by the 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 LifeVest®.

In 2015, the 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."

In 2021, the FDA approved the ASSURE® WCD for adult patients at risk for SCA who are not candidates for (or refuse) an ICD.

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 transvenous ICD (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, 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 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 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 lifesaving, 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 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 lifesaving, these rates 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 lifesaving, 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 VT or 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 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 an improvement in the net health outcome.

Subcutaneous ICDs
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 overall survival, 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 lifesaving, 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 overall survival, 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. .

WEARABLE CARDIAC DEFIBRILLATOR

Summary of Evidence

Overview of Wearable Cardioverter Defibrillator Versus Implantable Cardioverter Defibrillator
One randomized controlled trial (RCT) has compared WCD with usual guideline-based care and found no significant benefit to WCD over usual care. No studies have directly compared the performance of a WCD with a permanent ICD. One small study in an electrophysiology lab demonstrated that the WCD can correctly identify and terminate most induced ventricular arrhythmias. Similarly, a study of the ASSURE WCD in patients with cardiomyopathy found the WCD to detect all events recorded by an ICD with few false-positive shock alarms in a 30-day period. A cohort study of WCD use estimated that the percentage of successful resuscitations was approximately 70%. Multiple studies have demonstrated suboptimal adherence. Device failures were largely attributed to incorrect device use and/or nonadherence. A more recent registry study has reported a high compliance rate, although these results may be biased by self-selection. Collectively, this evidence indicates that the WCD can successfully detect and terminate arrhythmias in at least some patients but that overall performance in clinical practice might be inferior to a permanent ICD.

Temporary Contraindications
For individuals who have a temporary contraindication to an ICD who receive a WCD, the evidence includes prospective cohort studies and a technology assessment that assessed ICD devices, given the absence of evidence on WCD devices. 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 an 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 a RCT comparing WCD with guideline-based therapy, 2 cohort studies, and a systematic review. Relevant outcomes are overall survival, morbid events, functional outcomes, and treatment-related morbidity. The RCT reported no benefit of WCD over guideline-based therapy. The cohort study of 8453 patients showed that 252 shocks successfully terminated ventricular fibrillation or ventricular tachycardia (82% success rate), but without a control group, interpretation is difficult. Similarly, a retrospective cohort of Medicare data found that WCD use was associated with lower 1-year mortality than no WCD use, but potential biases were noted. Evidence from the systematic review was deemed of low to very low quality, and the reviewers had weak confidence in the reported estimates.

Post-Coronary Artery Bypass Graft Surgery at High Risk for Lethal Arrhythmias
For individuals who are post–coronary artery bypass graft surgery and are at high risk for lethal arrhythmias, the evidence includes an RCT for ICD and a registry study. 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. The registry study found survival benefits with WCD but had limited interpretation of data.

Awaiting Heart Transplantation at High Risk for Lethal Arrhythmias
For individuals who are awaiting heart transplantation and are at high risk for lethal arrhythmias, the evidence includes analyses of subsets of patients from the manufacturer registry, a subset from a prospective cohort study, and a case series. Relevant outcomes are overall survival, morbid events, functional outcomes, and treatment-related morbidity. These studies do not provide sufficient evidence to determine whether a WCD is of benefit compared with usual care.

Newly Diagnosed Nonischemic Cardiomyopathy
For individuals who have newly diagnosed nonischemic cardiomyopathy, the evidence includes an RCT for ICD and several retrospective analyses of WCD registry data. Relevant outcomes are overall survival, morbid events, functional outcomes, and treatment-related morbidity. The RCT found that prophylactic ICD placement for nonischemic cardiomyopathy did not improve mortality compared with usual care. Evidence from the retrospective analysis was not sufficient to determine whether WCD improves outcomes compared with usual care. Given the lack of evidence that ICD improves outcomes, WCD is not expected to improve outcomes under the conditions studied in these trials.

Peripartum Cardiomyopathy
For individuals who have peripartum cardiomyopathy, the evidence includes a retrospective registry data analysis and a small cohort study. Relevant outcomes are overall survival , morbid events, functional outcomes, and treatment-related morbidity. The registry study revealed that no shocks were delivered during use over an average of 124 days. The cohort study identified 4 episodes of appropriate electric shock over 133 days. 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 presents 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 health benefit plan. Benefit determinations should be based in all cases on the applicable health benefit plan language. Medical policies do not constitute a description of benefits. A member's health benefit plan governs which services are covered, which are excluded, which are subject to benefit limits, and which require preauthorization. There are different benefit plan designs in each product administered by Capital Blue Cross. Members and providers should consult the member's health benefit plan for information or contact Capital Blue Cross for benefit information.

VII. DISCLAIMER

TOP

Capital Blue Cross'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. If a provider or a member has a question concerning the application of this medical policy to a specific member's

plan of benefits, please contact Capital Blue Cross' Provider Services or Member Services. Capital Blue Cross 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.

Not medically necessary; therefore, not covered when used to ICD with substernal lead placement:

Procedure Codes								
0571T	0572T	0573T	0574T	0575T	0576T	0577T	0578T	0579T
0580T	0614T							

Covered when medically necessary:

Procedure Codes								
33216	33217	33218	33220	33223	33226	33230	33231	33240
33241	33243	33244	33249	33262	33263	33264	33270	33271
33272	33273	93260	93261	93282	93283	93284	93287	93289
93292	93295	93296	93297	93640	93641	93642	93644	93745
C1721	C1722	C1777	C1882	C1895	C1896	C1899	C7537	C7538
C7539	C7540	E0617	K0606					

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
I24.89	Other forms of acute ischemic heart disease
I25.5	Ischemic cardiomyopathy
I40.1	Isolated myocarditis
I42.0	Dilated cardiomyopathy
I42.1	Obstructive hypertrophic cardiomyopathy
I42.2	Other hypertrophic cardiomyopathy
I42.3	Endomyocardial (eosinophilic) disease

ICD-10 CM Diagnosis Codes	Description
I42.4	Endocardial fibroelastosis
I42.5	Other restrictive cardiomyopathy
I42.6	Alcoholic cardiomyopathy
I42.7	Cardiomyopathy due to drug and external agent
I42.8	Other cardiomyopathies
I42.9	Cardiomyopathy, unspecified
I43	Cardiomyopathy in diseases classified elsewhere
I45.81	Long QT syndrome
I45.89	Other specified conduction disorders
I46.2	Cardiac arrest due to underlying cardiac condition
I46.8	Cardiac arrest due to other underlying condition
I46.9	Cardiac arrest, cause unspecified
I47.0	Re-entry ventricular arrhythmia
I47.10	Supraventricular tachycardia, unspecified
I47.11	Inappropriate sinus tachycardia, so stated
I47.19	Other supraventricular tachycardia
I47.20	Ventricular tachycardia, unspecified
I47.29	Other ventricular tachycardia
I47.9	Paroxysmal tachycardia, unspecified
I49.01	Ventricular fibrillation
I49.02	Ventricular flutter
I49.9	Cardiac arrhythmia, unspecified
I50.1	Left ventricular failure, unspecified
I50.20	Unspecified systolic (congestive) heart failure
I50.21	Acute systolic (congestive) heart failure
I50.22	Chronic systolic (congestive) heart failure
I50.23	Acute on chronic systolic (congestive) heart failure
I50.30	Unspecified diastolic (congestive) heart failure
I50.31	Acute diastolic (congestive) heart failure
I50.32	Chronic diastolic (congestive) heart failure
I50.33	Acute on chronic diastolic (congestive) heart failure
I50.40	Unspecified combined systolic (congestive) and diastolic (congestive) heart failure
I50.41	Acute combined systolic (congestive) and diastolic (congestive) heart failure

ICD-10 CM Diagnosis Codes	Description
I50.42	Chronic combined systolic (congestive) and diastolic (congestive) heart failure
I50.43	Acute on chronic combined systolic (congestive) and diastolic (congestive) heart failure
I50.810	Right heart failure, unspecified
I50.811	Acute right heart failure
I50.812	Chronic right heart failure
I50.813	Acute on chronic right heart failure
I50.814	Right heart failure due to left heart failure
I50.82	Biventricular heart failure
I50.83	High output heart failure
I50.84	End stage heart failure
I50.89	Other heart failure
I50.9	Heart failure, unspecified
I51.7	Cardiomegaly
I5A	Non-ischemic myocardial injury (non-traumatic)
Q20.0	Common arterial trunk
Q20.1	Double outlet right ventricle
Q20.2	Double outlet left ventricle
Q20.3	Discordant ventriculoarterial connection
Q20.4	Double inlet ventricle
Q20.5	Discordant atrioventricular connection
Q20.6	Isomerism of atrial appendages
Q20.8	Other congenital malformations of cardiac chambers and connections
Q20.9	Congenital malformation of cardiac chambers and connections, unspecified
Q21.0	Ventricular septal defect
Q21.10	Atrial septal defect, unspecified
Q21.11	Secundum atrial septal defect
Q21.13	Coronary sinus atrial septal defect
Q21.14	Superior sinus venosus atrial septal defect
Q21.15	Inferior sinus venosus atrial septal defect
Q21.16	Sinus venosus atrial septal defect, unspecified
Q21.19	Other specified atrial septal defect
Q21.20	Atrioventricular septal defect, unspecified as to partial or complete
Q21.21	Partial atrioventricular septal defect

ICD-10 CM Diagnosis Codes	Description
Q21.22	Transitional atrioventricular septal defect
Q21.23	Complete atrioventricular septal defect
Q21.3	Tetralogy of Fallot
Q21.4	Aortopulmonary septal defect
Q21.8	Other congenital malformations of cardiac septa
Q21.9	Congenital malformation of cardiac septum, unspecified
Q22.0	Pulmonary valve atresia
Q22.1	Congenital pulmonary valve stenosis
Q22.2	Congenital pulmonary valve insufficiency
Q22.3	Other congenital malformations of pulmonary valve
Q22.4	Congenital tricuspid stenosis
Q22.5	Ebstein's anomaly
Q22.6	Hypoplastic right heart syndrome
Q22.8	Other congenital malformations of tricuspid valve
Q22.9	Congenital malformation of tricuspid valve, unspecified
Q23.0	Congenital stenosis of aortic valve
Q23.1	Congenital insufficiency of aortic valve
Q23.2	Congenital mitral stenosis
Q23.4	Hypoplastic left heart syndrome
Q23.8	Other congenital malformations of aortic and mitral valves
Q23.9	Congenital malformation of aortic and mitral valves, unspecified
Q24.0	Dextrocardia
Q24.1	Levocardia
Q24.2	Cor triatriatum
Q24.3	Pulmonary infundibular stenosis
Q24.4	Congenital subaortic stenosis
Q24.5	Malformation of coronary vessels
Q24.6	Congenital heart block
Q24.8	Other specified congenital malformations of heart
Q24.9	Congenital malformation of heart, unspecified
R55	Syncope and collapse
Z86.74	Personal history of sudden cardiac arrest

IX. REFERENCES

TOP

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X. POLICY HISTORY

TOP

MP 1.081	**5/2/2019 Consensus Review**. Policy statement unchanged. Reformatted table. Updated references.
	10/1/19 Admin update. Coding reviewed. Added procedure codes and diagnosis.
	1/21/2020 Minor review. Statement added**,** insertion of implantable cardioverter-defibrillator systems with substernal electrode is considered not medically necessary. Updated references. Coding reviewed. Effective 7/1/2020.
	5/20/2020- Administrative update. New code 0614T added. Product Variation, Benefit Variation, and Disclaimer updated.
	1/22/2021 Minor review. The following changes were made: • Removed abnormal blood pressure response to treadmill exercise in the setting of one of the following clinical modifiers: (1) >30 mm Hg LVOT gradient at rest; (b) late gadolinium enhancement on MRI; or (c) evidence of apical scarring for primary prevention under Implantable Defibrillators Adults. • Added Diagnosis of cardiac sarcoid and considered to be at high risk for sudden cardiac death (see Policy Guidelines section) • Changed left ventricular hypertrophy greater than 30 mm to Massive left ventricular hypertrophy based on age-specific norms under implantable defibrillators for pediatrics.

	• Removed one or more runs of nonsustained VT at heart rates of 120 beats per minute or greater on 24-hour Holter monitoring • Added section on Criteria for Implantable Cardioverter Defibrillator Implantation in Patients With Cardiac Sarcoid under policy guideline section. Policy Guidelines, Background, Rationale and References updated.
	9/7/2021 Administrative update. New code I5A added. Effective 10/1/2021
	07/20/2022 Minor review. Criteria for cardiac ion channelopathies moved from Policy Guidelines section to Policy Statement for both pediatric and adult. Removed abnormal blood pressure criteria point from pediatric Implantable Defibrillator section. Several changes made to Wearable Cardioverter Defibrillators section: • removed age limit • removed wear time limit • removed time period limit (up to 3 months) • heart transplant criteria revised to state "awaiting heart transplantation and considered high risk for arrthythmia • added "decline ICD placement" as criteria Policy Guidelines, Cross referenced policies and FEP language revised. Background, Rationale and References updated.
	08/15/2022 Administrative update. New ICD10 codes I47.20, I47.29, Q21.10, Q21.11, Q21.13, Q21.14, Q21.15, Q21.16, Q21.19, Q21.20, Q21.21, Q21.22, Q21.23 added to policy; I47.2 and Q21.2 removed. Effective 10/1/2022.
	11/29/2022 Admin update. Added new codes C7537, C7538, C7539, C7540
	06/29/2023 Consensus review. No change to policy statement. Background and Rationale updated. References added. Added CPT code 33727.
	09/11/2023 Administrative update. ICD10 code definitions revised due to new code. Added ICD10 codes I24.89, I47.10, I47.11 and I47.19. Removed ICD10 I47.1. Effective 10/1/2023

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