HIGHMARK Delaware
HEALTH OPTIONS

CLINICAL MEDICAL POLICY	
Policy Name:	Implantable Cardioverter-Defibrillator/Subcutaneous Implantable Cardioverter-Defibrillator (ICD/SICD)
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Products:	Highmark Health Options
Application:	All participating hospitals and providers
Page Number(s):	1 of 16

DISCLAIMER

Highmark Health Options medical policy is intended to serve only as a general reference resource regarding coverage for the services described. This policy does not constitute medical advice and is not intended to govern or otherwise influence medical decisions.

POLICY STATEMENT

Highmark Health Options may provide coverage under the medical-surgical benefits of the Company's Medicaid products for medically necessary Implantable Cardioverter-Defibrillator (ICD) and Subcutaneous Implantable Cardioverter-Defibrillator (S-ICD) procedures.

This policy is designed to address medical necessity guidelines that are appropriate for the majority of individuals with a particular disease, illness or condition. Each person's unique clinical circumstances warrant individual consideration, based upon review of applicable medical records.

The qualifications of the policy will meet the standards of the National Committee for Quality Assurance (NCQA) and the Delaware Department of Health and Social Services (DHSS) and all applicable state and federal regulations.

DEFINITIONS

ICD (Implantable Cardioverter-Defibrillator) – A device that is implanted inside the chest or abdomen to help treat and monitor irregular heart arrhythmias 24 hours a day. The device is transversely inserted into the heart chambers by wires with electrodes. If the device detects a heart arrhythmia, an electrical shock is sent out to correct the arrhythmia.

S-ICD (Subcutaneous Implantable Cardioverter-Defibrillator) – This device is a new technology in the evolution of ICD therapy that eliminates serious potential short- and long-term risks associated with placing electrical wires inside the heart or blood vessels.

S-ICD Electrogram (EGM) – A surface electrocardiogram (ECG) with specific lead placement to assure that the S-ICD reliably detects the patient's heart rhythm (QRS-complexes).

Sudden Cardiac Death (SCD) – A sudden stop in effective blood flow due to the failure of the heart to contract successfully. The blood stops flowing to the brain and other vital organs during sudden cardiac arrest (SCA). SCD is a life-threatening medical emergency that can cause brain damage or death without immediate treatment.

Ventricular Tachycardia (VT) – A type of heart rhythm disorder (arrhythmia) in which the lower chambers of the heart (ventricles) beat very quickly because of a problem in the heart's electrical system.

Ischemic Cardiomyopathy (IC) – Occurs when a heart muscle becomes weakened, which can result in a heart attack or coronary artery disease. Ischemic cardiomyopathy is defined as left ventricular systolic dysfunction associated with marked stenosis (at least 75% narrowing) of at least one of the three major coronary arteries, or a documented history of myocardial infarction.

Hypertrophic Cardiomyopathy (HCM) – A condition that occurs when heart muscle cells become enlarged and cause the walls of the ventricles to thicken.

Dilated Cardiomyopathy (DCM) – A condition that occurs when the heart becomes enlarged and cannot pump blood efficiently.

Brugada Syndrome – A hereditary condition that affects the electrical system of the heart, causing an abnormal heart rhythm. Patients with Brugada syndrome develop ventricular tachycardia.

Long QT Syndrome – A rare inherited disorder of the heart's electrical activity, in which delayed repolarization of the heart following a heartbeat increases the risk of episodes of torsades de pointes (TdP). **Short QT Syndrome** is an inherited disease of the heart's electrical system and consists of a short QT interval on an EKG that does not significantly change with heart rate, tall and peaked T waves, and a structurally normal heart.

Left Ventricular Ejection Fraction (LVEF) – The fraction of outbound blood pumped from the heart with each heartbeat. It is commonly measured by an echocardiogram and serves as a general measure of a person's cardiac function. A normal LVEF is 50% to 75%. A decreased LVEF is a result of cardiomyopathy, cardiac arrest, or heart failure.

Holter Monitor – A portable device for continuously monitoring various electrical activities of the cardiovascular system for at least 24 hours.

Unipolar Pacemaker – A pacemaker implanted with a single lead/electrode contacting with the heart.

Bipolar Pacemaker is a pacemaker with a dual lead/electrode contacting with the heart.

PROCEDURES

1. Medical Necessity Guidelines
   A. **ICD**

An ICD is considered medically necessary when the following criteria are met:

1) The patient must be 18 years of age or older: AND
2) The prescribing doctor must be a cardiologist, electrophysiologist, or cardiac surgeon; AND
3) The device is used in **primary prevention** for patients with the following:
   a. The patient is considered to be at high risk for sudden cardiac death (SCD) but has not experienced life-threatening VT or VF; AND
   b. The patient has one of the following conditions and is considered to be at high risk for SCD; AND
      1. Long QT syndrome with recurrent symptoms; OR
      2. Congenital and hypertrophic cardiomyopathies; OR
      3. Catecholaminergic polymorphic ventricular tachycardia; OR
      4. Brugada syndrome; OR
      5. Arrhythmogenic right ventricular dysplasia/cardiomyopathy (ARVD/C); OR
      6. Short QT syndrome; AND
   c. The patient has IC with NYHA functional Class II or Class III (see Attachment D) symptoms, MI history for at least 40 days before ICD treatment, and LVEF of ≤ 35 percent; OR
   d. The patient has IC with NYHA functional Class I symptoms (see Attachment D), MI history for at least 40 days before ICD treatment, and LVEF of ≤ 30 percent; OR
   e. The patient has non-ischemic DCM and LVEF of ≤ 35 percent after reversible causes have been excluded, and the response to optimal medical therapy has been adequately determined; OR
   f. The patient has HCM with one or more major risk factor(s) for sudden cardiac death (history of premature HCM-related sudden death in one or more first-degree relatives younger than 50 years; left ventricular hypertrophy greater than 30 mm; one or more runs of non-sustained VT at heart rates of 120 beats per minute or greater on 24-hour Holter monitoring; prior unexplained syncope inconsistent with neurocardiogenic origin) and judged to be at high risk for SCD by a physician experienced in caring for HCM patients; OR

4) The device is used in **secondary prevention** for patients with the following:
   a. A patient has a history of a life-threatening episode of ventricular tachyarrhythmia after reversible causes (e.g., acute ischemia) have been excluded; OR
   b. A patient with episodes of spontaneous, sustained ventricular tachyarrhythmia or ventricular fibrillation in the presence of a structural heart disease.

B. **Subcutaneous ICD (S-ICD) for adult patients**

THE USE OF AN S-ICD MAY BE CONSIDERED MEDICALLY NECESSARY FOR ADULTS WHO MEET THE INDICATIONS LISTED ABOVE (SECTION 1.A) AND MEET ALL OF THE FOLLOWING CRITERIA:

1) The patient must be 18 years of age or older; AND
2) The prescribing doctor must be a cardiologist, electrophysiologist, or cardiac surgeon; AND
3) The patient passed the S-ICD Electrogram (EGM) screening; AND

4) The patient has no indication of cardiac rhythms requiring pacing/resynchronization therapy; AND
5) The patient has inadequate vascular access; OR
6) The patient has one of the following conditions which puts the patient at high risk for complications from transvenous ICD implantation:
    a. Prior device infection (e.g., ICD); OR
    b. Active systemic infection (e.g., bacteremia, open ulcers, and sepsis) or prior systemic infection related to device removal; OR
    c. Hemodialysis; OR
    d. Chronic vascular occlusion
    e. Hypercoagulable state
    f. < 50 years of age with the expected longevity of ICD placement over 10 years duration

C. **S-ICD for pediatric patients**

THE USE OF AN S-ICD MAY BE CONSIDERED MEDICALLY NECESSARY FOR PEDIATRIC PATIENTS WHO MEET THE INDICATIONS LISTED ABOVE (SECTION 1.A) AND MEET ALL OF THE FOLLOWING CRITERIA:

1) *The patient must be between 10 to 18 years of age; AND
2) The prescribing doctor must be a cardiologist, electrophysiologist, or cardiac surgeon; AND
3) The patient passed the S-ICD electrogram (EGM) screening; AND
4) The patient has no indication of cardiac rhythms requiring pacing/resynchronization therapy; AND
5) The patient has inadequate vascular access; OR
6) The patient has one of the following conditions which puts the patient at high risk for complications from transvenous ICD implantation:
    a. Prior device infection (e.g., ICD); OR
    b. Active systemic infection (e.g., bacteremia, open ulcers, and sepsis) or prior systemic infection related to device removal; OR
    c. Hemodialysis; OR
    d. Chronic vascular occlusion
    e. Hypercoagulable state;

    AND
7) The patient has survived cardiac arrest, after reversible causes have been excluded; AND
8) Congenital heart disease with recurrent syncope of undetermined origin in the presence of ventricular dysfunction or inducible ventricular arrhythmias; OR
9) HCM with one or more major risk factor(s) for sudden cardiac death (history of premature HCM-related sudden death in one or more first-degree relatives younger than 50 years; massive left ventricular hypertrophy based on age-specific norms; prior unexplained syncope inconsistent with neurocardiogenic origin) and judged to be at high risk for sudden cardiac death by a physician experienced in the care of patients with HCM; AND
10) The patient has one of the following conditions and is considered to be at high risk for SCD:
    a. Pediatric Long QT syndrome with recurrent symptoms; OR
    b. Congenital and hypertrophic cardiomyopathies; OR
    c. Catecholaminergic polymorphic ventricular tachycardia; OR
    d. Brugada syndrome
    e. Arrhythmogenic right ventricular dysplasia (ARVC); OR
    f. Inherited arrhythmia syndromes

*** Requests for S-ICD in pediatric patients who are 10 years of age and younger will require a case-by-case review by a medical director.**

Medical records must be made available to support the evaluation and treatment of a specific cardiac condition and prior cardiac events.

2. Contraindications
   All ICD therapy devices are contraindicated for patients experiencing a tachyarrhythmia with transient or reversible causes including, but not limited to, the following:
   A. Acute myocardial infarction
   B. Drug intoxication
   C. Smoking
   D. Drowning
   E. Electric shock
   F. Electrolyte imbalance
   G. Hypoxia
   H. Sepsis
   I. Patients with incessant ventricular tachycardia (VT) or ventricular fibrillation (VF)
   J. Patients with a primary disorder of chronic atrial tachyarrhythmia with no concomitant VT or VF

3. When the ICD and S-ICD are not covered
   For conditions other than those listed above, scientific evidence has not been established.
   Examples include but are not limited to:
   A. Patient with an acute myocardial (MI) within the past 40 days; OR
   B. Patient with ventricular tachyarrhythmia due to a reversible disorder in the absence of structural heart disease; OR
   C. Patient with irreversible brain damage; OR
   D. Patient with cardiogenic shock or symptomatic hypotension while in a stable baseline rhythm; OR
   E. Patient without reasonable expectation of survival with an acceptable functional status for at least one year, even if they meet all ICD criteria from above; OR
   F. Syncope in the absence of structural heart disease; OR
   G. Patient with any disease, other than cardiac disease, associated with a likelihood of survival less than one year; OR
   H. Patient has NYHA Class IV (see Attachment D) heart failure and is not eligible for a combination of cardiac resynchronization therapy and ICD; OR
   I. Patient has had a cardiac revascularization procedure in past three months (coronary artery bypass graft [CABG] or percutaneous transluminal coronary angioplasty [PTCA]) or are candidates for a cardiac revascularization procedure
   J. The device should not be used in patients with ventricular tachycardia or ventricular fibrillation amenable to surgical or ablative treatment.

Additional criteria that is not covered for use of an S-ICD
Examples include but are not limited to:
A. Patients with an S-ICD who have no indications for unipolar pacemakers; OR
B. The device should not be used in a patient possessing the following:
   1) Incessant VT or VF; OR
   2) Ventricular antitachycardia pacing or antibradycardia pacing; OR
   3) Cardiac resynchronization therapy; OR
   4) Symptomatic bradycardia

4. Place of Service
   This procedure requires an outpatient surgical stay.

5. Post-payment Audit Statement
   The medical record must include documentation that reflects the medical necessity criteria and is subject to audit by Highmark Health Options at any time pursuant to the terms of your provider agreement.

New York Heart Association (NYHA) Heart Failure Classification Table

Class	Patient Symptoms
I	No limitation of physical activity. Ordinary physical activity does not cause undue fatigue, palpitation, dyspnea (shortness of breath).
II	Slight limitation of physical activity. Comfortable at rest. Ordinary physical activity results in fatigue, palpitation, dyspnea (shortness of breath).
III	Marked limitation of physical activity. Comfortable at rest. Less than ordinary activity causes fatigue, palpitation, or dyspnea.
IV	Unable to carry on any physical activity without discomfort. Symptoms of heart failure at rest. If any physical activity is undertaken, discomfort increases.

GOVERNING BODIES APPROVAL

The first ICD devices were approved by the FDA in 1988 and 1989. The FDA made approvals on an individual basis and granted premarket approvals (PMA) for ICDs for the indications of providing antitachycardia pacing and ventricular defibrillation for automated treatment of life-threatening ventricular arrhythmias.

On February 26, 2008, Boston Scientific received FDA approval for the Confient implantable cardioverter-defibrillator (ICD) to help protect patients at risk of SCD.

On September 28, 2012, the S-ICD system by Cameron Health, Inc. was approved by the FDA "to provide defibrillation therapy for the treatment of life-threatening ventricular tachyarrhythmia in patients who do not have symptomatic bradycardia, continual (incessant) ventricular tachycardia, or spontaneous frequently recurring ventricular tachycardia that is reliably terminated with anti-tachycardia pacing." In June 2012, the S-ICD system was acquired by Boston Scientific Corporation. This was the first FDA approval of a subcutaneous ICD.

On February 2, 2015, the FDA approved Boston Scientific to launch the world's longest lasting ICD. The implanted device has a new line of extended longevity (EL) ICD models which is projected to last nearly 12 years.

On September 14, 2015, the FDA approved the first implantable cardioverter-defibrillator that was designed to be used safely in patients who undergo an MRI. This ICD was developed by Medtronic and is called the Evera MRI ICD.

Boston Scientific Corp. announced on March 17, 2015 that it received FDA approval, as well as the CE mark, for its Emblem™ S-ICD system. The Emblem is the next-generation S-ICD. According to the company, the Emblem device is 20% thinner than the S-ICD, and its battery will last 40% longer.

On August 9, 2016, the FDA granted market approval for the Emblem MRI subcutaneous implantable cardioverter-defibrillator (S-ICD), as well as magnetic resonance (MR) conditional labeling for all previously implanted Emblem S-ICD systems. The new device is the latest addition to the Boston Scientific's growing line of ImageReady MR-conditional electrophysiology devices, which enables patients to undergo MRIs safely.

CODING REQUIREMENTS

Procedure Codes

CPT/HCPCS Codes	Description
33216	Insertion of a single transvenous electrode, permanent pacemaker or implantable defibrillator
33217	Insertion of 2 transvenous electrode, permanent pacemaker or implantable defibrillator
33218	Repair of single transvenous electrode, permanent pacemaker or implantable defibrillator
33220	Repair of 2 transvenous electrode, permanent pacemaker or implantable defibrillator
33223	Relocation of skin pocket for implantable defibrillator

33224	Insertion of pacing electrode, cardiac venous system, for left ventricular pacing, with attachment to previously placed pacemaker or pacing implantable defibrillator pulse generator (including revision of pocket, removal, insertion, and/or replacement of existing generator)
33225	Insertion of pacing electrode, cardiac venous system, for left ventricular pacing, at time of insertion of implantable defibrillator or pacemaker pulse generator (e.g., for upgrade to dual chamber system) (List separately in addition to code for primary procedure)
33230	Insertion of implantable defibrillator pulse generator only, with existing dual leads
33231	Insertion of implantable defibrillator pulse generator only, with existing multiple leads
33240	Insertion of implantable defibrillator pulse generator only, with existing single lead
33241	Removal of implantable defibrillator pulse generator only
33243	Removal of single or dual chamber pacing cardioverter-defibrillator electrode(s); by thoracotomy
33244	Removal of single or dual chamber pacing cardioverter-defibrillator electrode(s); by transvenous extraction
33249	Insertion or replacement of permanent pacing cardioverter-defibrillator system with transvenous lead(s), single or dual chamber
33262	Removal of implantable defibrillator pulse generator with replacement of implantable defibrillator pulse generator, single lead system
33263	Removal of implantable defibrillator pulse generator with replacement of pacing cardioverter-defibrillator pulse generator; dual lead system
33264	Removal of implantable defibrillator pulse generator with replacement of pacing cardioverter-defibrillator pulse generator; multiple lead system
33270	Insertion or replacement of permanent subcutaneous implantable defibrillator system, with subcutaneous electrode, including defibrillation threshold evaluation, induction of arrhythmia, evaluation of sensing for arrhythmia termination, and programming or reprogramming of sensing or therapeutic parameters, when performed
33271	Insertion of subcutaneous implantable defibrillator electrode
33272	Removal of subcutaneous implantable defibrillator electrode
33273	Repositioning of previously implanted subcutaneous implantable defibrillator electrode
93260	Programming device evaluation S-ICD, Implantable subcutaneous lead defibrillator system
93261	Implantable subcutaneous lead defibrillator system
93644	Electrophysiologic evaluation of subcutaneous implantable defibrillator
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)
C1899	Lead, pacemaker/cardioverter-defibrillator combination (implantable)

Diagnosis Codes

ICD-10 Codes	Description
B57.0	Chagas' disease, Acute Chagas' disease with heart involvement
B57.2	Chagas' disease, Chagas' disease (chronic) with heart involvement
D86.85	Sarcoidosis of other sites , Sarcoid myocarditis
I01.1	Acute rheumatic endocarditis
I40.1	Isolated myocarditis
I42.0	Dilated cardiomyopathy, congestive cardiomyopathy
I42.1	Obstructive hypertrophic cardiomyopathy, Hypertrophic subaortic stenosis (idiopathic)
I42.2	Other hypertrophic cardiomyopathy, nonobstructive hypertrophic cardiomyopathy
I42.3	Cardiomyopathy, endomyocardial (eosinophilic) disease
I42.4	Endocardial fibroelastosis, congenital cardiomyopathy, Elastomyofibrosis
I42.8	Other cardiomyopathies [Arrhythmogenic right ventricular dysplasia]
I42.9	Cardiomyopathy, unspecified
I45.81	Long QT syndrome
I45.89	Other specified conduction disorders [Atrioventricular (AV) dissociation]
I45.9	Conduction disorder, unspecified
I46.2	Cardiac arrest due to underlying cardiac condition (code first underlying cardiac condition)
I46.8	Cardiac arrest due to other underlying cardiac condition (code first underlying cardiac condition)
I47.1	Supraventricular tachycardia
I47.2	Ventricular tachycardia
I47.9	Paroxysmal tachycardia, unspecified
I49.01	Ventricular fibrillation
I49.02	Ventricular flutter
I49.3	Ventricular premature depolarization
I50.1	Left ventricular failure, unspecified (ICD-10 updates 2018)
I51.0	Cardiac septal defect, acquired
I51.4	Myocarditis, unspecified
Q20.0	Congenital malformations of cardiac chambers and connections; Common arterial trunk
Q20.1	Congenital malformations of cardiac chambers and connections; Double outlet left ventricle
Q20.2	Congenital malformations of cardiac chambers and connections; Double outlet left ventricle
Q20.3	Congenital malformations of cardiac chambers and connections; Discordant ventriculoarterial connection
Q20.4	Congenital malformations of cardiac chambers and connections; Double inlet ventricle
Q20.5	Congenital malformations of cardiac chambers and; Discordant atrioventricular connection
Q20.6	Congenital malformations of cardiac chambers and connections; Isomerism of atrial appendages
Q20.8	Other congenital malformations of cardiac chambers and connections

Q20.9	Congenital malformations of cardiac chambers and connections code range, unspecified
Q21.0	Congenital malformations of cardiac septa; Ventricular septal defect
Q21.1	Congenital malformations of cardiac septa; Atrial septal defect
Q21.2	Congenital malformations of cardiac septa; Atrioventricular septal defect
Q21.3	Congenital malformations of cardiac septa; Tetralogy of Fallot
Q21.4	Congenital malformations of cardiac septa; Aortopulmonary septal defect
Q21.8	Other congenital malformations of cardiac septa
Q21.9	Congenital malformations of cardiac septa, unspecified
Q22.0	Congenital malformations of pulmonary and tricuspid valves, Pulmonary valve atresia
Q22.1	Congenital malformations of pulmonary and tricuspid valves, Congenital pulmonary valve stenosis
Q22.2	Congenital malformations of pulmonary and tricuspid valves, congenital pulmonary valve insufficiency
Q22.3	Congenital malformations of pulmonary and tricuspid valves, other congenital malformations of pulmonary valve
Q22.4	Congenital malformations of pulmonary and tricuspid valves, congenital tricuspid stenosis
Q22.5	Congenital malformations of pulmonary and tricuspid valves, Ebstein's anomaly
Q22.6	Congenital malformations of pulmonary and tricuspid valves, Hypoplastic right heart syndrome
Q22.8	Other congenital malformations of pulmonary and tricuspid valves
Q22.9	Congenital malformations of pulmonary and tricuspid valves, unspecified
Q23.0	Congenital malformations of aortic and mitral valves, congenital stenosis of aortic valve
Q23.1	Congenital malformations of aortic and mitral valves, congenital insufficiency of aortic valve
Q23.2	Congenital malformations of aortic and mitral valves, congenital mitral stenosis
Q23.3	Congenital malformations of aortic and mitral valves, congenital mitral insufficiency
Q23.4	Congenital malformations of aortic and mitral valves, hypoplastic left heart syndrome
Q23.8	Other congenital malformations of aortic and mitral valves
Q23.9	Congenital malformations of aortic and mitral valves, unspecified
Q24.0	Other congenital malformations of heart, Dextrocardia
Q24.1	Other congenital malformations of heart, Levocardia
Q24.2	Other congenital malformations of heart, Cor triatriatum
Q24.3	Other congenital malformations of heart, Pulmonary infundibular stenosis
Q24.4	Other congenital malformations of heart, congenital subaortic stenosis
Q24.5	Other congenital malformations of heart, malformation of coronary vessels
Q24.6	Other congenital malformations of heart, congenital heart block
Q24.8	Other specified congenital malformations of heart (Brugada syndrome)
Q24.9	Congenital malformations of heart, unspecified
T82.110A	Mechanical complication of cardiac electronic device, Breakdown (mechanical) of cardiac electrode
T82.111A	Mechanical complication of cardiac electronic device, Breakdown (mechanical) of cardiac pulse generator (battery), initial encounter

T82.111D	Mechanical complication of cardiac electronic device, Breakdown (mechanical) of cardiac pulse generator (battery), subsequent encounter
T82.111S	Mechanical complication of cardiac electronic device, Breakdown (mechanical) of cardiac pulse generator (battery), sequela
T82.119A	Mechanical complication of cardiac electronic device, Breakdown (mechanical) of unspecified cardiac electronic device, initial encounter
T82.119D	Mechanical complication of cardiac electronic device, Breakdown (mechanical) of, unspecified cardiac electronic device, subsequent encounter
T82.119S	Mechanical complication of cardiac electronic device, Breakdown (mechanical) of, unspecified cardiac electronic device, sequela
T82.120A	Mechanical complication of cardiac electronic device, displacement of cardiac electrode, initial encounter
T82.120D	Mechanical complication of cardiac electronic device, displacement of cardiac electrode, subsequent encounter
T82.120S	Mechanical complication of cardiac electronic device, displacement of cardiac electrode, sequela
T82.121A	Mechanical complication of cardiac electronic device, displacement of cardiac pulse generator (battery), initial encounter
T82.121D	Mechanical complication of cardiac electronic device, displacement of cardiac pulse generator (battery), subsequent encounter
T82.121S	Mechanical complication of cardiac electronic device, displacement of cardiac pulse generator (battery), sequela
T82.128A	Mechanical complication of cardiac electronic device, displacement of other cardiac electronic device, initial encounter
T82.128D	Mechanical complication of cardiac electronic device, displacement of cardiac pulse generator (battery), subsequent encounter
T82.128S	Mechanical complication of cardiac electronic device, displacement of cardiac pulse generator (battery), sequela
T82.129A	Mechanical complication of cardiac electronic device, displacement of unspecified cardiac device, initial encounter
T82.190A	Mechanical complication of cardiac electronic device, other mechanical complication of cardiac electrode, initial encounter
T82.190D	Mechanical complication of cardiac electronic device, other mechanical complication of cardiac electrode, subsequent encounter
T82.190S	Mechanical complication of cardiac electronic device, sequela
T82.191A	Mechanical complication of cardiac electronic device, other mechanical complication of cardiac pulse generator (battery), initial encounter
T82.191D	Mechanical complication of cardiac electronic device, other mechanical complication of cardiac pulse generator (battery), subsequent encounter
T82.191S	Mechanical complication of cardiac electronic device, other mechanical complication of cardiac pulse generator (battery), sequela
T82.198A	Mechanical complication of cardiac electronic device, other mechanical complication of other cardiac electronic device, initial encounter
T82.198D	Mechanical complication of cardiac electronic device, other mechanical complication of other cardiac electronic device, subsequent encounter
T82.198S	Mechanical complication of cardiac electronic device, other mechanical complication of other cardiac electronic device, sequela

T82.199A	Mechanical complication of cardiac electronic device, other mechanical complication of unspecified cardiac device, initial encounter
T82.199D	Mechanical complication of cardiac electronic device, other mechanical complication of unspecified cardiac device, subsequent encounter
T82.199S	Mechanical complication of cardiac electronic device, other mechanical complication of unspecified cardiac device, sequela
T82.7XXA	Infection and inflammatory reaction due to other cardiac and vascular devices, implants and grafts, initial encounter
T82.7XXD	Infection and inflammatory reaction due to other cardiac and vascular devices, implants and grafts, subsequent encounter
T82.7XXS	Infection and inflammatory reaction due to other cardiac and vascular devices, implants and grafts, sequela
T82.827A	Fibrosis due to cardiac and vascular prosthetic devices, implants and grafts, initial encounter
T82.827D	Fibrosis due to cardiac and vascular prosthetic devices, implants and grafts, subsequent encounter
T82.827S	Fibrosis due to cardiac and vascular prosthetic devices, implants and grafts, sequela
T82.837A	Hemorrhage due to cardiac and vascular prosthetic devices, implants and grafts, initial encounter
T82.837D	Hemorrhage due to cardiac and vascular prosthetic devices, subsequent encounter
T82.837S	Hemorrhage due to cardiac and vascular prosthetic devices, sequela
T82.847A	Pain due to cardiac and vascular prosthetic devices, initial encounter
T82.847D	Pain due to cardiac and vascular prosthetic devices, subsequent encounter
T82.847S	Pain due to cardiac and vascular prosthetic devices, sequela
T82.867A	Thrombosis due to cardiac and vascular prosthetic devices, initial encounter
T82.867D	Thrombosis due to cardiac and vascular prosthetic devices, subsequent encounter
T82.867S	Thrombosis due to cardiac and vascular prosthetic devices, sequela
T82.897A	Other specified complication of cardiac and vascular prosthetic devices, initial encounter
T82.897D	Other specified complication of cardiac and vascular prosthetic devices, subsequent encounter
T82.897S	Other specified complication of cardiac and vascular prosthetic devices, sequela
Z82.41	Family history of sudden cardiac death
Z82.49	Family history of ischemic heart disease and other diseases of the circulatory system
Z84.81	Family history of genetic disease
Z86.74	Personal history of sudden cardiac arrest
Z87.74	Personal history of congenital malformations of heart and circulatory system

REIMBURSEMENT

Participating facilities will be reimbursed per their Highmark Health Options contract.

SUMMARY OF LITERATURE

The American College of Cardiology released a report (2016) designating sudden cardiac arrest (SCA) as a leading cause of death in the United States. SCA is the abrupt loss of heart function and leads to sudden cardiac death (SCD). Implantable cardioverter-defibrillator therapy (ICD) is a preventive treatment for specific patients that are at risk of SCD or have experienced SCA. Fatal ventricular arrhythmias (e.g., ventricular tachycardia [VT] and ventricular fibrillation [VF]) are the cause of 80 percent of SCDs (NICE, 2007). According to the National Institute of Health and Clinical Excellence (2007), the remaining 20 percent of SCDs are due to many different conditions, including:

- Cardiomyopathies (10-15%)
- Other structural defects (less than 5%)
- Bradycardia

The high out-of-hospital mortality causes public health concern, which led to the need for a solution—the implantable cardioverter-defibrillator (ICD). An ICD is considered medically necessary in certain VT/VF patient populations that are at high risk of SCD (Ganz, 2016). Initially, the ICD was indicated for secondary prevention to prevent reoccurring SCAs after a patient has survived one or more resuscitations (Zitron, 2012). Primary prevention refers to ICD implantation in patients who are at risk of SCD but have not experienced an episode of sustained VT/VF (Zitron, 2012). Research shows the vast majority of today's ICDs are for primary prevention which is superior to secondary prevention and conventional anti-arrhythmic drug therapy in patients that meet indication criteria (Ganz, 2016). Twenty-two percent of patients receive an ICD for secondary prevention, while the vast majority of patients receive an ICD for primary prevention (Hayes, 2013). There are continuous improvements to the technology for ICD therapy which is demonstrated by the newer devices. Some of the ICD models have pacemaker functionality, "backup" pacing for bradycardia occurrences, storage of detected arrhythmic events, and electrophysiological testing features (American Heart Association, 2016).

Although there are many patients who are at a high risk of SCD, some patient populations are not indicated for ICD therapy. Patients with symptomatic bradycardia are not candidates for ICD therapy because the device is not indicated for slow heart pacing (Ganz, 2016). An ICD serves arrhythmias that are irregular, uncontrolled, or very fast (i.e., VT/VF). According to the New England Journal of Medicine, ICDs do not provide treatment to patients with many conditions and situations including but not limited to the following (Ganz, 2016):

- Acute MIs (less than 40 days). If a patient receives an ICD within 40 days of an acute MI, the patient is at high risk of non-sudden cardiac death which negates the benefit of ICDs (Aronow, 2014).
- Ventricular tachyarrthymias due to reversible causes without a structural heart disease. Examples: electrolyte imbalance, drugs, or trauma.
- Patients with NYHA Class IV heart failure that are refractory to optimal medical treatment who are not candidates for cardiac transplantation or cardiac resynchronization therapy.

Mortality rates have shown improvement, but ICD transvenous lead systems have major long-term risks of lead malfunction, inappropriate shocks, infection, pneumothorax, hemothorax, and cardiac tamponade (Gold, 2013). Studies show over 20 percent of patients will have a lead failure within ten years (Gold, 2013). The shocks delivered by ICD therapy are painful and can be caused by common atrial fibrillations (e.g., rapid heart rate from exercise) (Fogoros, 2016). In other cases, the device would fail to function normally due to lead problems and requires surgical intervention and massive recalls (Fogoros, 2016).

The subcutaneous implantable cardioverter-defibrillator (S-ICD) is a new technology in ICD therapy. The S-ICD is similar to the traditional ICD, except for the lead system which remains outside of the chest cavity and requires no vein attachment. Clinical trials show S-ICDs have lowered the large occurrence of transvenous lead failure and infections delivered from a conventional ICD (Bardy, 2010). The S-ICD may be medically necessary in patients that cannot gain access to veins for a host of reasons (Chang, 2014). In addition to the S-ICD improvements, there are significant limitations surrounding the use of S-ICDs. The device cannot provide pacemaker or resynchronization therapy which can be provided by traditional ICDs (Chang, 2014). Also, studies suggest that between 8 and 15 percent of patients are ineligible for an S-ICD due to susceptibility to T-wave over sensing, which causes a high risk of inappropriate shocks (Weinstock, 2016).

The device was initially motivated by cases of children with congenital heart diseases and are considered in younger patients due to the expected longevity of the implanted leads, desire to avoid chronic transvenous leads, congenital anomalies, and physically active and athletic statuses (Weinstock, 2016). S-ICDs are most appropriate for the use in pediatric populations because there are major complications related to the ICD transvenous leads within children (Bharucha, 2015). Although there is large pediatric consideration for the use of S-ICDs, there is a small amount of evidence-based guidelines (Bharucha, 2015). The S-ICD has a relatively larger generator, compared to the traditional ICD, which poses concerns in smaller pediatric patients and infants (Berul, 2011). In addition to the limited literature on the use of S-ICDs in children, the technology is limited to detecting SCA and does not have the ability to provide anti-bradycardia or tachycardia pacing, which are two conditions in a large amount of the pediatric population (Griksaitis, 2013). The efficacy of S-ICDs has been established in older children and in post-pubertal teens due to the size of the device, anatomy of a growing child, and psychological impact (Griksaitis, 2013). According to the Doernbecher Children's Hospital (2014), "The S-ICD promises to be a very useful advancement for teens and some pre-teens but is not yet appropriate for very small children." Many pediatric and cardiology societies and journals believe it is only a matter of time before the technology is applicable to smaller children.

There is little evidence on comparative clinical outcomes for both types of ICDs over a long period of therapy. There are successful detection rates and conversions of ventricular tachycardia, but additional clinical trials are needed on different population samples to show the effects the technology has on health outcomes.

POLICY SOURCE(S)

Algarra, M., Santiago, P., Tercedor, L., et al. Implantable-Cardioverter Defibrillator in Pediatric Population. University Hospital Virgen de las Nieves de Granada, Spain; September 2011. Accessed on January 17, 2017.

American Heart Association. Implantable Cardioverter Defibrillator (ICD); December 21, 2016. Accessed on January 23, 2017.

American College of Cardiology. New Report Outlines Ten Measures for the Prevention of Sudden Cardiac Death: American Heart Association/American College of Cardiology Clinical Performance and Quality Measures; December 19, 2016. Accessed on January 20, 2017.

Aronow, W.S. Indications for Implantable Cardioverter-Defibrillator Therapy and Recommendations for Implantable Cardioverter-Defibrillator Therapy in Patients not included or not well represented in

Clinical Trials. Cardiology Division, Department of Medicine, New York Medical College/Westchester Medical Center, Valhalla, NY, USA; July 14, 2014. Accessed on January 20, 2017.

Balaji, S. New heart defibrillator is a game-changer for tweens, teens with heart arrhythmia, March 7, 2014. Doernbecher Children's Hospital: Oregon Health & Science University. Accessed on February 6, 2017.

Bardy, G.H., Smith, W.M., Hood, M.A., et al. An Entirely Subcutaneous Implantable Cardioverter-Defibrillator. The New England Journal of Medicine; July 2010; 363:36-44. Accessed on January 13, 2017.

Berul, C.I., Moak, J.P. Implantable Cardioverter-Defibrillators in Children: Innovation to Design a Pediatric ICD: Division of Cardiology. The Journal of Innovations in Cardiac Rhythm Management; February 4, 2011. Accessed on February 6, 2017.

Birnie, H.D., Sambell, C., Johansen, H., et al. Use of implantable cardioverter defibrillators in Canadian and US survivors of out-of-hospital cardia arrest. Canadian Medical Association Journal; August 2007; 177(1). Accessed on January 19, 2017.

Bharucha, T., Lee, K.J., Daubeney, E.F.P., Nugent, A.W., et al. Sudden Death in Childhood Cardiomyopathy: Results from a Long-Term National Population-Based Study. Journal of the American College of Cardiology (JACC), Volume 65, Issue 21, June 2015. Accessed on January 20, 2017.

Chang, P.M., Doshi, R., Saxon, L.A. Circulation: American Heart Association; 129:e644-e646; June 9, 2014. Accessed on January 20, 2017.

Fogoros, R.N. Implantable Cardioverter Defibrillator Complications: Surgical and post-surgical complications with ICDs. Verywell; January 4, 2016. Accessed on January 20, 2017.

Ganz, L.I. General Principles of the implantable cardioverter-defibrillator; December 2016. Accessed on January 17, 2017.

Griksaitis, M.J., Rosengarten, J.A., Gnanapragasam, J.P., et al. Implantable cardioverter defibrillator therapy in paediatric practice: a single-centre UK experience with focus on subcutaneous defibrillation, January 20, 2013. Oxford Academic: Europace; 15 (4): 523-530. Accessed on February 7, 2017.
Journal of the American College of Cardiology (JACC). 2016 AHA/ACC Clinical Performance and Quality Measures for Prevention of Sudden Cardiac Death; December 2016. Accessed January 19, 2017.

Journal of the American College of Cardiology (JACC). Study Addresses Appropriateness of ICD Implantation: ACC News Story; May 14, 2015. Accessed on January 19, 2017.

National Institute of Health and Clinical Excellence (NICE). Implantable cardioverter defibrillators for arrhythmias: Review of Technology Appraisal 11; July 2007; MidCity Place, London. Accessed on January 20, 2017.

Pennsylvania HealthChoices. Managed Care Operations Memorandum: Technology Assessment Group Coverage Decisions; May 23, 2016. Accessed on January 17, 2017.

Poole, J.E., Gold, M.R. Who Should Receive the Subcutaneous Implanted Defibrillator? Circulation: Arrhythmia and Electrophysiology; December 17, 2013. Accessed on January 20, 2017.

Raghavan, S.S. Pediatric Long QT Syndrome: Pediatrics: Cardiac Disease and Critical Care Medicine. Medscape; June 26, 2014. Accessed on February 6, 2017.

S-ICD (Subcutaneous Implantable Cardioverter Defibrillator; Boston Scientific Corp.) for Prevention of Sudden Cardiac Death, 2013. Accessed on January 12, 2017.

U.S. Food & Drug Administration (FDA). Subcutaneous Implantable Defibrillator (S-ICD) System – P110042; September 28, 2012. Accessed on January 20, 2017.

Weinstock, J., Selan, J., Majithia, A. Subcutaneous implantable cardioverter defibrillators, 2016. Accessed on January 12, 2017.

Zitron, E., Thomas, D., Katus, H.A., Becker, R. Cardioverter defibrillator therapy in the primary and secondary prevention of sudden cardiac death. Applied Cardiopulmonary Pathophysiology; 16: 174-191, 2012. Accessed January 20, 2017.

Policy History

Date	Activity
02/07/2017	Initial policy developed
06/27/2017	QI/UM Committee approval
08/09/2017	Added Disclaimer Statement in opening of medical policy. EHS Revisions: Added Issue Date to opening policy box; updated Operational Guidelines; added 'Informational in Attachment D.
09/01/2017	Provider effective date
10/23/2017	2018 Coding Revisions: Diagnosis code I50.1 has been updated
12/20/2017	Annual Review: No Changes
03/13/2018	QI/UM Annual Review Approval
04/20/2018	Revision: Removed the word 'Covered' from the procedure and diagnosis code tables in Attachments B & C
05/15/2018	New effective date
06/19/2018	Revision: Deleted procedure codes 33282, 33284 & C1764 as not appropriate for this policy. Revised place of service from inpatient to outpatient.
09/11/2018	QI/UM Committee approval
05/15/2018	Provider effective date
03/12/2019	Annual Review Revisions: Removed the word 'Covered' from the procedure and diagnosis code tables in Attachments B & C; Deleted procedure codes 33282, 33284 & C1764 as not appropriate for this policy. Revised place of service from inpatient to outpatient.
03/12/2019	QI/UM Committee Review Approval
05/06/2019	Provider effective date