02-33000-34

Original Effective Date: 12/15/13

Reviewed: 04/26/24

Revised: 01/01/25

# Subject: Implantable Cardioverter Defibrillators/ Cardiac Contractility Modulation (CCM) Therapy

THIS MEDICAL COVERAGE GUIDELINE IS NOT AN AUTHORIZATION, CERTIFICATION, EXPLANATION OF BENEFITS, OR A GUARANTEE OF PAYMENT, NOR DOES IT SUBSTITUTE FOR OR CONSTITUTE MEDICAL ADVICE. ALL MEDICAL DECISIONS ARE SOLELY THE RESPONSIBILITY OF THE PATIENT AND PHYSICIAN. BENEFITS ARE DETERMINED BY THE GROUP CONTRACT, MEMBER BENEFIT BOOKLET, AND/OR INDIVIDUAL SUBSCRIBER CERTIFICATE IN EFFECT AT THE TIME SERVICES WERE RENDERED. THIS MEDICAL COVERAGE GUIDELINE APPLIES TO ALL LINES OF BUSINESS UNLESS OTHERWISE NOTED IN THE PROGRAM EXCEPTIONS SECTION.

Position Statement	Billing/Coding	Reimbursement	Program Exceptions	<u>Definitions</u>	Related Guidelines
<u>Other</u>	References	<u>Updates</u>			

### **DESCRIPTION:**

Implantable cardioverter defibrillators (ICDs) monitor a patient's heart rate, recognize ventricular fibrillation or ventricular tachycardia (VT), and deliver an electric shock to terminate these arrhythmias to reduce the risk of sudden cardiac death (SCD). Indications for ICD placement can be broadly subdivided into (1) secondary prevention, i.e., use in patients who have experienced a potentially lifethreatening 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 ventricular fibrillation.

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

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

Several automatic ICDs have been approved by the U.S. Food and Drug Administration (FDA) through the premarket approval process.

Cardiac contractility modulation (CCM) therapy is a proposed method to treat patients that have moderate to severe heart failure and are not resonding to medical management. The Optimizer Smart system is an example of a cardiac contractility modulation device.

Summary and Analysis of Evidence: The AHA/ACC/HFSA Guideline for the Management of Heart Failure: A Report of the American College of Cardiology/American Heart Association Joint Committee on Clinical Practice Guidelines (2022) states, "Significant gaps exist despite evolving evidence and treatment strategies in patients with HF. Table 33 provides selected, common issues that should be addressed in future clinical research." Table 33 includes "Safety and efficacy of cardiac contractility modulation...in patients with HF". Patients with a high risk of SCD due to ischemic or nonischemic cardiomyopathy in adulthood who receive transvenous implantable cardioverter defibrillator (T-ICD) placement for primary prevention, the evidence includes multiple well-designed and well-conducted randomized controlled trials (RCTs) as well as systematic reviews of these trials. Multiple RCTs have shown a benefit in overall mortality for patients with ischemic cardiomyopathy and reduced ejection fraction. RCT assessing early ICD use following recent myocardial infarction (MI) did not support a benefit for immediate versus delayed implantation for at least 40 days. The evidence is sufficient to determine that the technology results in an improvement in the net health outcome. High risk of SCD due to hypertrophic cardiomyopathy (HCM) for patients in adulthood who receive T-ICD placement for primary prevention, the evidence includes several large registry studies. In the studies, the annual rate of appropriate ICD discharge ranged from 3.6% to 5.3%. Given the long-term high risk of SCD in patients with HCM, with the assumption that appropriate shocks are life-saving, these studies are considered adequate evidence to support the use of T-ICDs in patients with HCM. The evidence is sufficient to determine that the technology results in an improvement in the net health outcome. Patients at 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. 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. The evidence is sufficient to determine that the technology results in an improvement in the net health outcome. Patients with symptomatic life-threatening sustained VT or ventricular fibrillation (VF) or who have been resuscitated from sudden cardiac arrest (secondary prevention) who receive T-ICD placement, the evidence includes multiple well-designed and well-conducted RCTs as well as systematic reviews of these trials. 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. Patients 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 S-ICD placement, the evidence includes an RCT, nonrandomized studies, and case series. Case series have reported high rates of detection and successful conversion of VF, and inappropriate shock rates in the range reported for T-ICD. Given the need for ICD placement in this population at risk for SCD, with the assumption that appropriate shocks are life-saving, these studies are considered adequate evidence to support the use of S-ICDs in patients with contraindication to T-ICD. The evidence is sufficient to determine that the technology results in an improvement in the net health outcome. Patients who need an ICD and have no indications for antibradycardia pacing or antitachycardia pacingresponsive arrhythmias with no contraindication to a T-ICD, who receive S-ICD placement, the evidence includes 1 RCT, nonrandomized studies, and case series. 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. 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. 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.

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

### **POSITION STATEMENT:**

## **Implantable Cardioverter Defibrillators**

#### **ADULTS**

The use of the automatic implantable cardioverter defibrillator (ICD) meets the definition of medical necessity in adults who meet **ONE** of the following criteria:

**Primary Prevention** (use of ICDs in members who are considered at high risk for sudden cardiac death, but who have not yet experienced life-threatening ventricular tachycardia (VT) or ventricular fibrillation (VF))

- Ischemic cardiomyopathy with New York Heart Association (NYHA) functional Class II or Class III
  symptoms, a history of myocardial infarction at least 40 days before ICD treatment, AND left
  ventricular ejection fraction of 35% or less; OR
- Ischemic cardiomyopathy with NYHA functional Class I symptoms, a history of myocardial infarction at least 40 days before ICD treatment, AND left ventricular ejection fraction of 30% or less; OR
- Nonischemic dilated cardiomyopathy AND left ventricular ejection fraction of 35% or less, after reversible causes have been excluded, AND the response to optimal medical therapy has been adequately determined; OR
- 4. Hypertrophic cardiomyopathy (HCM) with 1 or more major risk factors for sudden cardiac death (history of premature HCM-related sudden death in 1 or more first-degree relatives younger than 50 years; left ventricular hypertrophy greater than 30 mm; 1 or more runs of nonsustained ventricular tachycardia at heart rates of 120 beats per minute or greater on 24-hour Holter monitoring; prior unexplained syncope inconsistent with neurocardiogenic origin) and judged to be at high risk for sudden cardiac death by a physician experienced in the care of members with HCM OR
- 5. Diagnosis of **ONE** of the following cardiac ion channelopathies and considered to be at high risk for sudden cardiac death:
  - congenital long QT syndrome
  - Brugada syndrome
  - short QT syndrome **OR**

- catecholaminergic polymorphic ventricular tachycardia.
- 6. Diagnosis of cardiac sarcoid and considered to be at high risk for sudden cardiac death.

**Secondary Prevention** (use of ICDs in members who have experienced a potentially life-threatening episode of near sudden cardiac death)

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

The use of the ICD is considered **experimental or investigational** in primary prevention members who do not meet the above criteria or have had ANY of the following:

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

The evidence is insufficient to determine the effects of the technology on health outcomes.

The use of the ICD for secondary prevention is considered **experimental or investigational** for members who do not meet the criteria for secondary prevention. The evidence is insufficient to determine the effects of the technology on health outcomes.

#### **PEDIATRICS**

The use of the ICD meets the definition of medical necessity in children who meet ANY of the following criteria:

- A. Survivors of cardiac arrest, after reversible causes have been excluded; OR
- B. Symptomatic, sustained ventricular tachycardia in association with congenital heart disease in members who have undergone hemodynamic and electrophysiologic evaluation; **OR**
- C. Congenital heart disease with recurrent syncope of undetermined origin in the presence of either ventricular dysfunction or inducible ventricular arrhythmias; **OR**
- D. HCM with 1 or more major risk factors for sudden cardiac death (history of premature HCM-related sudden death in 1 or more first-degree relatives younger than 50 years; massive left ventricular hypertrophy based on age-specific norms; prior unexplained syncope inconsistent with neurocardiogenic origin) and judged to be at high risk for sudden cardiac death by a physician experienced in the care of members with HCM; **OR**
- E. Diagnosis of any **ONE** of the following cardiac ion channelopathies and considered to be at high risk for sudden cardiac death:
  - congenital long QT syndrome;

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

The use of the ICD is considered **experimental or investigational** for all other indications in pediatric members. The evidence is insufficient to determine the effects of the technology on health outcomes.

### SUBCUTANEOUS IMPLANTABLE CARDIOVERTER DEFIBRILLATORS

The use of a subcutaneous ICD **meets the definition of medical necessity** for adults or children who meet the criteria for ICD implantation for primary or secondary prevention **AND** meet **ALL** of the following criteria:

- Have a contraindication to a transvenous ICD due to one or more of the following: (1) lack of
  adequate vascular access; (2) compelling reason to preserve existing vascular access (ie, need
  for chronic dialysis; younger members with anticipated long-term need for ICD therapy); or (3)
  history of need for explanation of a transvenous ICD due to a complication, with ongoing need
  for ICD therapy
- Have no indication for antibradycardia pacing; AND
- Do not have ventricular arrhythmias that are known or anticipated to respond to antitachycardia pacing.

The use of a subcutaneous ICD is considered **experimental or investigational** for individuals who do not meet the criteria outlined above. The evidence is insufficient to determine the effects of the technology on health outcomes.

### **Cardiac Contractility Modulation (CCM) Therapy**

The use of cardiac contractility modulation therapy is considered **experimental or investigational** for all indications. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

### **BILLING/CODING INFORMATION:**

# **CPT Coding:**

33216	Insertion of a single transvenous electrode, permanent pacemaker or implantable defibrillator
33217	Insertion of 2 transvenous electrodes, permanent pacemaker or implantable
	defibrillator
33218	Repair of single transvenous electrode, permanent pacemaker or implantable
	defibrillator
33220	Repair of 2 transvenous electrodes for permanent pacemaker or implantable
	defibrillator
33223	Revision 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 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 (eg, 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 implantable defibrillator electrode(s); by thoracotomy
33244	Removal of single or dual chamber Implantable defibrillator electrode(s); by transvenous extraction
33249	Insertion or replacement of permanent implantable defibrillator system with transvenous lead(s), single or dual chamber
33262	Removal of implantable defibrillator pulse generator with replacement of pacing cardioverter-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 (in person) with iterative adjustment of the implantable device to test the function of the device and select optimal permanent programmed values with analysis, review and report by a physician or other qualified health care professional; implantable subcutaneous lead defibrillator system
93261	Interrogation device evaluation (in person) with analysis, review and report by a physician or other qualified health care professional, includes connection, recording and disconnection per patient encounter; implantable subcutaneous lead defibrillator system

93640	Electrophysiologic evaluation of single or dual chamber pacing cardioverter-
	defibrillator leads including defibrillation threshold evaluation (induction of
	arrhythmia, evaluation of sensing and pacing for arrhythmia termination) at time
	of initial implantation or replacement;
93641	Electrophysiologic evaluation of single or dual chamber pacing cardioverter-
	defibrillator leads including defibrillation threshold evaluation (induction of
	arrhythmia, evaluation of sensing and pacing for arrhythmia termination) at time
	of initial implantation or replacement; with testing of single or dual chamber
	pacing cardioverter-defibrillator pulse generator
93642	Electrophysiologic evaluation of single or dual chamber transvenous pacing
	cardioverter-defibrillator (includes defibrillation threshold evaluation, induction
	of arrhythmia, evaluation of sensing and pacing for arrhythmia termination, and
	programming or reprogramming of sensing or therapeutic parameters)
93644	Electrophysiologic evaluation of subcutaneous implantable defibrillator (includes
	defibrillation threshold evaluation, induction of arrhythmia, evaluation of sensing
	for arrhythmia termination, and programming or reprogramming of sensing or
	therapeutic parameters)
0408T	Insertion or replacement of permanent cardiac contractility modulation system,
	including contractility evaluation when performed, and programming of sensing
	and therapeutic parameters; pulse generator with transvenous electrodes
	(Investigational)
0409T	Insertion or replacement of permanent cardiac contractility modulation system,
	including contractility evaluation when performed, and programming of sensing
	and therapeutic parameters; pulse generator only (Investigational)
0410T	Insertion or replacement of permanent cardiac contractility modulation system,
	including contractility evaluation when performed, and programming of sensing
	and therapeutic parameters; atrial electrode only (Investigational)
0411T	Insertion or replacement of permanent cardiac contractility modulation system,
	including contractility evaluation when performed, and programming of sensing
	and therapeutic parameters; ventricular electrode only (Investigational)
0412T	Removal of permanent cardiac contractility modulation system; pulse generator
	only (Investigational)
0413T	Removal of permanent cardiac contractility modulation system; transvenous
	electrode (atrial or ventricular) (Investigational)
0414T	Removal and replacement of permanent cardiac contractility modulation system
	pulse generator only (Investigational)
0415T	Repositioning of previously implanted cardiac contractility modulation
	transvenous electrode, (atrial or ventricular lead) (Investigational)
0416T	Relocation of skin pocket for implanted cardiac contractility modulation pulse
	generator (Investigational)
0417T	Programming device evaluation (in person) with iterative adjustment of the
	implantable device to test the function of the device and select optimal
	permanent programmed values with analysis, including review and report,
	implantable cardiac contractility modulation system (Investigational)
U41/I	implantable device to test the function of the device and select optimal permanent programmed values with analysis, including review and report,

0418T	Interrogation device evaluation (in person) with analysis, review and report,
	includes connection, recording and disconnection per patient encounter;
	implantable cardiac contractility modulation system (Investigational)
0915T	Insertion of permanent cardiac contractility modulation-defibrillation system
00101	component(s), including fluoroscopic guidance, and evaluation and programming
	of sensing and therapeutic parameters; pulse generator and dual transvenous
	electrodes/leads (pacing and defibrillation) (Investigational)
0916T	Insertion of permanent cardiac contractility modulation-defibrillation system
	component(s), including fluoroscopic guidance, and evaluation and programming
	of sensing and therapeutic parameters; pulse generator only (Investigational)
0917T	Insertion of permanent cardiac contractility modulation-defibrillation system
	component(s), including fluoroscopic guidance, and evaluation and programming
	of sensing and therapeutic parameters; single transvenous lead (pacing or
	defibrillation) only (Investigational)
0918T	Insertion of permanent cardiac contractility modulation-defibrillation system
	component(s), including fluoroscopic guidance, and evaluation and programming
	of sensing and therapeutic parameters; dual transvenous leads (pacing and
	defibrillation) only (Investigational)
0919T	Removal of a permanent cardiac contractility modulation-defibrillation system
	component(s); pulse generator only (Investigational)
0920T	Removal of a permanent cardiac contractility modulation-defibrillation system
	component(s); single transvenous pacing lead only (Investigational)
0921T	Removal of a permanent cardiac contractility modulation-defibrillation system
	component(s); single transvenous defibrillation lead only (Investigational)
0922T	Removal of a permanent cardiac contractility modulation-defibrillation system
	component(s); dual (pacing and defibrillation) transvenous leads only
0000T	(Investigational)
0923T	Removal and replacement of permanent cardiac contractility modulation-
0924T	defibrillation pulse generator only (Investigational)  Repositioning of previously implanted cardiac contractility modulation-defibrillation
09241	transvenous electrode(s)/lead(s), including fluoroscopic guidance and
	programming of sensing and therapeutic parameters (Investigational)
0925T	Relocation of skin pocket for implanted cardiac contractility modulation-
09231	defibrillation pulse generator (Investigational)
0926T	Programming device evaluation (in person) with iterative adjustment of the
03201	implantable device to test the function of the device and select optimal permanent
	programmed values with analysis, including review and report, implantable cardiac
	contractility modulation-defibrillation system (Investigational)
0927T	Interrogation device evaluation (in person) with analysis, review, and report,
	including connection, recording, and disconnection, per patient encounter,
	implantable cardiac contractility modulation-defibrillation system (Investigational)
0928T	Interrogation device evaluation (remote), up to 90 days, cardiac contractility
	modulation-defibrillation system with interim analysis and report(s) by a physician
	or other qualified health care professional (Investigational)
0929T	Interrogation device evaluation (remote), up to 90 days, cardiac contractility
	modulation-defibrillation system, remote data acquisition(s), receipt of
	transmissions, technician review, technical support, and distribution of results
	(Investigational)

0930T	Electrophysiologic evaluation of cardiac contractility modulation-defibrillator leads, including defibrillation-threshold evaluation (induction of arrhythmia, evaluation of sensing and therapy for arrhythmia termination), at time of initial implantation or replacement with testing of cardiac contractility modulation-defibrillator pulse generator (Investigational)
0931T	Electrophysiologic evaluation of cardiac contractility modulation-defibrillator leads, including defibrillation-threshold evaluation (induction of arrhythmia, evaluation of sensing and therapy for arrhythmia termination), separate from initial implantation or replacement with testing of cardiac contractility modulation-defibrillator pulse generator (Investigational)

# **HCPCS Coding**

G0448	Insertion or replacement of a permanent pacing cardioverter-defibrillator system with transvenous lead(s), single or dual chamber with insertion of pacing electrode, cardiac venous system, for left ventricular pacing
K1030	External recharging system for battery (internal) for use with implanted cardiac contractility modulation generator, replacement only (Investigational)

# **ICD-10 Diagnosis Codes That Support Medical Necessity:**

125.5	Ischemic cardiomyopathy
142.1, 142.2	Hypertrophic cardiomyopathy
142.8	Other cardiomyopathies
142.9	Cardiomyopathy, unspecified
I45.81	Long QT syndrome
145.89	Other specified conduction disorders
146.2 – 146.9	Cardiac arrest
149.01	Ventricular fibrillation
149.9	Cardiac arrhythmia, unspecified
Q20.0 – Q20.9	Congenital malformations of cardiac chambers and connections
Q21.0 - Q21.9	Congenital malformations of cardiac septa
Q22.0 – Q22.9	Congenital malformations of pulmonary and tricuspid valves
Q23.0 – Q23.9	Congenital malformations of aortic and mitral valves
Q24.0 – Q24.9	Other congenital malformations of heart
·	

# **LOINC Codes:**

The following information may be required documentation to support medical necessity: physician history and physical, conservative treatment plan, physician progress notes, and all laboratory studies.

<b>Documentation Table</b>	LOINC	LOINC	LOINC Time Frame Modifier Codes
	Codes	Time Frame	Narrative
		Modifier Code	
Physician history and	28626-0	18805-2	Include all data of the selected type that
physical			represents observations made six months or
			fewer before starting date of service for the
			claim.

Attending physician progress note	18741-9	18805-2	Include all data of the selected type that represents observations made six months or fewer before starting date of service for the claim.
Medication Current	19009-0	18805-2	Include all data of the selected type that represents observations made six months or fewer before starting date of service for the claim.
Current, Discharge, or administered medications	34483-8	18805-2	Include all data of the selected type that represents observations made six months or fewer before starting date of service for the claim.

### **REIMBURSEMENT INFORMATION:**

Refer to section entitled **POSITION STATEMENT**.

# **PROGRAM EXCEPTIONS:**

Federal Employee Program (FEP): Follow FEP guidelines.

State Account Organization (SAO): Follow SAO guidelines.

**Medicare Advantage products:** The following National Coverage Determination (NCD) was reviewed on the last guideline reviewed date: Implantable Automatic Defibrillators (20.4) located at cms.gov.

If this Medical Coverage Guideline contains a step therapy requirement, in compliance with Florida law 627.42393, members or providers may request a step therapy protocol exemption to this requirement if based on medical necessity. The process for requesting a protocol exemption can be found at <a href="Coverage">Coverage</a> <a href="Protocol Exemption Request">Protocol Exemption Request</a>.

### **DEFINITIONS:**

New York Heart Association (NYHA) Functional Classification:

NYHA Class	
1	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.

### **RELATED GUIDELINES:**

<u>Wearable and Non-Wearable Cardioverter-Defibrillators (WCD) for the Prevention of Sudden Cardiac</u>

Death, 01-93000-30

### **OTHER:**

None applicable.

### **REFERENCES:**

- 1. Abraham WT, Kuck KH, et al. A Randomized Controlled Trial to Evaluate the Safety and Efficacy of Cardiac Contractility Modulation. JACC Heart Fail. 2018 Oct;6(10):874-883. PMID: 29754812.
- Al-Khatib SM, Stevenson WG, et al, 2017 AHA/ACC/HRS Guideline for Management of Patients With Ventricular Arrhythmias and the Prevention of Sudden Cardiac Death: A Report of the American College of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines and the Heart Rhythm Society. Circulation. 2017 Oct 30.
- 3. American Heart Association, Classes of Heart Failure; accessed at heart.org.
- Anker SD, Borggrefe M, et al. Cardiac contractility modulation improves long-term survival and hospitalizations in heart failure with reduced ejection fraction. Eur J Heart Fail. 2019 Sep;21(9):1103-1113. PMID: 30652394.
- 5. Baher A, Valderrabano M. Management of ventricular tachycardia in heart failure. Methodist Debakey Cardiovasc J. 2013 Jan-Mar;9(1):20-5.
- 6. Blue Cross Blue Shield Association Evidence Positioning System®. 7.01.44 Implantable Cardioverter Defibrillators, 06/23.
- Blue Cross Blue Shield Association Technology Evaluation Center (TEC). Use of implantable cardioverter-defibrillators for prevention of sudden death in patients at high risk for ventricular arrhythmia. TEC Assessments 2002; 17(Tab 10).
- 8. Blue Cross Blue Shield Association Technology Evaluation Center (TEC). Use of implantable cardioverter-defibrillators for prevention of sudden death in patients at high risk for ventricular arrhythmia. TEC Assessments 2004; 19(Tab 19).Bardy GH, Smith WM, Hood MA, et al. An entirely subcutaneous implantable cardioverter-defibrillator. N Engl J Med. 2010; 363(1):36-44.
- Boersma L, Barr C, Knops R, et al. Implant and Midterm Outcomes of the Subcutaneous Implantable Cardioverter-Defibrillator Registry: The EFFORTLESS Study. J Am Coll Cardiol. 2017 Aug 15:70(7):830-841.
- 10. Campbell CM, Kahwash R, et al. Optimizer Smart in the treatment of moderate-to-severe chronic heart failure. Future Cardiol. 2020 Jan;16(1):13-25. doi: 10.2217/fca-2019-0044. Epub 2019 Dec 9. PMID: 31825245.
- 11. Centers for Medicare & Medicaid Services (CMS). National Coverage Determination (NCD) for Implantable Automatic Defibrillators (20.4), accessed at cms.gov.
- 12. Cheng A, Dalal D, Butcher B, Norgard S, Zhang Y, Dickfeld T, Eldadah ZA, Ellenbogen KA, Guallar E, Tomaselli GF.Prospective observational study of implantable cardioverter-defibrillators in primary prevention of sudden cardiac death: study design and cohort description. J Am Heart Assoc. 2013 Feb 22;2(1):e000083. doi: 10.1161/JAHA.112.000083.
- 13. ClinicalTrials.gov. Cardiac Contractility Modulation Therapy in Subjects With Heart Failure With Preserved Ejection Fraction; accessed May 2022.

- 14. ClinicalTrials.gov. A Prospective, Multi-center, Non-randomized, Single Arm Open Label Study of 620 Subjects Receiving the OPTIMIZER Smart With CCM Therapy as Standard of Care; accessed May 2022.
- 15. Colucci WS. Investigational and emerging strategies for management of heart failure. In: UpToDate, Gottlieb SS, Dardas TF (Eds.), UpToDate, Waltham, MA; accessed at uptodate.com.
- 16. Dabiri Abkenari L, Theuns DA, Valk SD, Van Belle Y, de Groot NM, Haitsma D, Muskens-Heemskerk A, Szili-Torok T, Jordaens L. Clinical experience with a novel subcutaneous implantable defibrillator system in a single center. Clin Res Cardiol. 2011 Sep;100(9):737-44.
- 17. Epstein AE, DiMarco JP, Ellenbogen KA, et al. 2012 ACCF/AHA/HRS focused update incorporated into the ACCF/AHA/HRS 2008 guidelines for device-based therapy of cardiac rhythm abnormalities: a report of the American College of Cardiology Foundation/American Heart Association Task Force on Practice Guidelines and the Heart Rhythm Society. J Am Coll Cardiol. Jan 22 2013;61(3):e6-75.
- 18. Friedman DJ, Parzynski CS, Varosy PD, et al. Trends and In-Hospital Outcomes Associated With Adoption of the Subcutaneous Implantable Cardioverter Defibrillator in the United States. JAMA Cardiol. 2016 Nov 1;1(8):900-911.
- 19. Gersh BJ, Maron BJ, Bonow RO et al. 2011 ACCF/AHA guideline for the diagnosis and treatment of hypertrophic cardiomyopathy: a report of the American College of Cardiology Foundation/American Heart Association Task Force on Practice Guidelines. Circulation 2011; 124(24):e783-831.
- 20. Giallauria F, Cuomo G, et al. A comprehensive individual patient data meta-analysis of the effects of cardiac contractility modulation on functional capacity and heart failure-related quality of life. ESC Heart Fail. 2020 Oct;7(5):2922-2932.PMID:32700809.
- Gold MR, Aasbo JD, El-Chami MF, et al. Subcutaneous implantable cardioverter-defibrillator Post-Approval Study: Clinical characteristics and perioperative results. Heart Rhythm. 2017 Oct;14(10):1456-1463.
- 22. Heidenreich PA, Bozkurt B, et al. 2022 AHA/ACC/HFSA Guideline for the Management of Heart Failure: A Report of the American College of Cardiology/American Heart Association Joint Committee on Clinical Practice Guidelines. J Am Coll Cardiol. 2022 May 3;79(17):e263-e421.
- 23. Hunt SA, Abraham WT, Chin MH, et al. 2009 focused update incorporated into the ACC/AHA 2005 guidelines for the diagnosis and management of heart failure in adults: a report of the American College of Cardiology Foundation/American Heart Association Task Force on Practice Guidelines. J Am Coll Cardiol. 2009; 53:e1–90.
- 24. Impulse Dynamics. Optimizer® System Clinical Evidence Dossier; May 2020.
- 25. Jessup M AW, Casey DE et al. 2009 focused update: ACCF/AHA Guidelines for the Diagnosis and Management of Heart Failure in Adults: a report of the American College of Cardiology Foundation/American Heart Association Task Force on Practice Guidelines: developed in collaboration with the International Society for Heart and Lung Transplantation. Circulation 2009; 119(14):1977-2016.
- 26. Khairy P, Van Hare GF, Balaji S, et al. PACES/HRS expert consensus statement on the recognition and management of arrhythmias in adult congenital heart disease: developed in partnership between the Pediatric and Congenital Electrophysiology Society (PACES) and the Heart Rhythm Society (HRS). Endorsed by the governing bodies of PACES, HRS, the American College of Cardiology (ACC), the American Heart Association (AHA), the European Heart Rhythm Association (EHRA), the Canadian Heart Rhythm Society (CHRS), and the International Society for Adult Congenital Heart Disease (ISACHD). Can J Cardiol. Oct 2014;30(10):e1-e63; accessed at hrsonline.org 10/15.
- 27. Kober L, Thune JJ, Nielsen JC, et al. Defibrillator implantation in patients with nonischemic systolic heart failure. N Engl J Med. Sep 29 2016;375(13):1221-1230.
- 28. Kuschyk J, Falk P, et al. Long-term clinical experience with cardiac contractility modulation therapy delivered by the Optimizer Smart system. Eur J Heart Fail. 2021 May 17. doi: 10.1002/ejhf.2202. PMID: 34002440.0.

- 29. Kusumoto FM, Calkins H, Boehmer J, et al. HRS/ACC/AHA Expert Consensus Statement on the Use of Implantable Cardioverter-Defibrillator Therapy in Patients Who Are Not Included or Not Well Represented in Clinical Trials. J Am Coll Cardiol. 2014;64(11):1143-1177.
- 30. Lambiase PD, Barr C, Theuns DAMJ, et al; on behalf of the EFFORTLESS Investigators. Worldwide experience with a totally subcutaneous implantable defibrillator: Early results from the EFFORTLESS S-ICD Registry. Eur Heart J. 2014 Mar 26 [Epub ahead of print].
- 31. Lobodzinski SS. Subcutaneous implantable cardioverter-defibrillator (S-ICD). Cardiol J. 2011;18(3):326-31.
- 32. Mando R, Goel A, et al. Outcomes of Cardiac Contractility Modulation: A Systematic Review and Meta-Analysis of Randomized Clinical Trials. Cardiovasc Ther. 2019 Jun 17;2019:9769724. PMID:31772622.
- 33. Manganelli G, Fiorentino A, et al. Use of Cardiac Contractility Modulation in an Older Patient with Non-Ischemic Dilated Cardiomyopathy: A Case Report. Clin Pract. 2021 Nov 3;11(4):835-840.
- 34. Masarone D, Petraio A, et al. Use of Cardiac Contractility Modulation as Bridge to Transplant in an Obese Patient With Advanced Heart Failure: A Case Report. Front Cardiovasc Med. 2022 Feb 16;9:833143.
- 35. Matteucci A, Bonacchi G, et al. Matching Imaging and Remodulation Effects: Benefits of Cardiac Contractility Modulation Shown by Global Longitudinal Strain: A Case Report. Clin Pract. 2022 Feb 17;12(1):113-117.
- 36. Mithani AA, Kath H, et al. Characteristics and Early Clinical Outcomes of Patients Undergoing Totally Subcutaneous vs. Transvenous Single Chamber Implantable Cardioverter Defibrillator Placement. Comparative Study Europace. 2018 Feb1;20(2):308-314.PMID:28383717.
- 37. Müller D, Remppis A, et al. Clinical effects of long-term cardiac contractility modulation (CCM) in subjects with heart failure caused by left ventricular systolic dysfunction. Clin Res Cardiol. 2017 Nov;106(11):893-904. PMID: 28685207.
- 38. National Institute for Health and Care Excellence (NICE). Implantable cardioverter defibrillators and cardiac resynchronisation therapy for arrhythmias and heart failure [TA314]. 2014; accessed at nice.org.
- 39. National Institute of Health Care and Excellence (NICE). Cardiac contractility modulation device implantation for heart failure. Interventional procedures guidance [IPG655] Published date: June 2019; accessed at nice.org.
- 40. Saxon LA. The subcutaneous implantable defibrillator: A new technology that raises an existential question for the implantable cardioverter-defibrillator. Circulation. 2013;128(9):938-940.
- 41. Sharif ZI, Galand V, et al. Evolving Cardiac Electrical Therapies for Advanced Heart Failure Patients. Circ Arrhythm Electrophysiol. 2021 Apr;14(4):e009668.
- 42. Towbin JA, McKenna WJ, et al. 2019 HRS Expert Consensus Statement on Evaluation, Risk Stratification, and Management of Arrhythmogenic Cardiomyopathy. Heart Rhythm. 2019 Nov;16(11):e301-e372.
- 43. Tracy CM, Epstein AE, Darbar D, et al. 2012 ACCF/AHA/HRS Focused Update Incorporated Into the ACCF/AHA/HRS 2008 Guidelines for Device-Based Therapy of Cardiac Rhythm Abnormalities A Report of the American College of Cardiology Foundation/American Heart Association Task Force on Practice Guidelines and the Heart Rhythm Society. J Am Coll Cardiol. 2013;61(3):e6-e75.
- 44. U.S. Food and Drug Administration (FDA); accessed at fda.gov.
- 45. Visco V, Esposito C, et al. A Multistep Approach to Deal With Advanced Heart Failure: A Case Report on the Positive Effect of Cardiac Contractility Modulation Therapy on Pulmonary Pressure Measured by CardioMEMS. Front Cardiovasc Med. 2022 Apr 4;9:874433.

- 46. Weiss R, Knight BP, Gold MR, Leon AR, Herre JM, Hood M, Rashtian M, Kremers M, Crozier I, Lee KL, Smith W, Burke MC. Safety and Efficacy of a Totally Subcutaneous Implantable-Cardioverter Defibrillator. Circulation. 2013 Aug 27;128(9):944-953.
- 47. Wiegn P, Chan R, et al. Safety, Performance, and Efficacy of Cardiac Contractility Modulation Delivered by the 2-Lead Optimizer Smart System: The FIX-HF-5C2 Study. Circ Heart Fail. 2020 Apr;13(4):e006512.
- 48. Yancy CW, Jessup M, et al. 2013 ACCF/AHA Guideline for the Management of Heart Failure: A Report of the American College of Cardiology Foundation/American Heart Association Task Force on Practice Guidelines. J Am Coll Cardiol. 2013 Oct 15;62(16):e147-239.
- 49. Yancy CW, Jessup M, et al. 2017 ACC/AHA/HFSA Focused Update of the 2013 ACCF/AHA Guideline for the Management of Heart Failure: A Report of the American College of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines and the Heart Failure Society of America. J Card Fail. 2017 Aug;23(8):628-651.

### **COMMITTEE APPROVAL:**

This Medical Coverage Guideline (MCG) was approved by the Florida Blue Medical Policy and Coverage Committee on 04/26/24.

### **GUIDELINE UPDATE INFORMATION:**

12/15/13	New Medical Coverage Guideline.
11/15/14	Annual review; position statements unchanged; references updated.
01/01/15	Annual coding update: added 33270, 33271, 33272, 33273, 93260, 93261, and 93644;
	deleted 0319T, 0320T, 0321T, 0322T,0323T, 0324T, 0325T, 0326T, 0327T, and 0328T;
	revised 33215, 33216, 33217, 33218, 33220, 33223, 33224, 33225, 33230, 33231, 33240,
	33241, 33243, 33244, 33249, 33262, 33263, and 33264.
11/01/15	Revision: ICD-9 Codes deleted.
12/15/15	Revision; position statements, coding, and references updated; formatting changes.
07/15/17	Review; position statements maintained and references updated; formatting changes.
08/15/18	Review; position maintained; description section, coding, program exception, and
	references updated.
08/15/20	Review; Adult primary prevention criteria updated and references updated.
08/15/21	
30, 20, 21	Revision; Cardiac contractility modulation therapy position statement added; policy title,
33, 13, 21	description, coding, and references updated.
04/01/22	
	description, coding, and references updated.
04/01/22	description, coding, and references updated.  Quarterly CPT/HCPCS Update. Code K1030 added.
04/01/22 07/15/22	description, coding, and references updated.  Quarterly CPT/HCPCS Update. Code K1030 added.  Review: Position statements maintained; references updated.
04/01/22 07/15/22 10/01/22	description, coding, and references updated.  Quarterly CPT/HCPCS Update. Code K1030 added.  Review: Position statements maintained; references updated.  Annual ICD-10 coding update. Code I47.2 deleted.
04/01/22 07/15/22 10/01/22 05/25/23	description, coding, and references updated.  Quarterly CPT/HCPCS Update. Code K1030 added.  Review: Position statements maintained; references updated.  Annual ICD-10 coding update. Code I47.2 deleted.  Update to Program Exceptions section.