02-33000-34

Original Effective Date: 12/15/13

Reviewed: 06/23/22

Revised: 05/25/23

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.

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 SCD. Indications for ICD placement can be broadly subdivided into (1) secondary prevention, ie, use in patients who have experienced a potentially life-threatening episode of VT (near SCD); and (2) primary prevention, ie, 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. 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 previous myocardial infarction and reduced injection fraction. S-ICD systems have been approved 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.

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.

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.

Per the FDA, "The Optimizer Smart System includes an implantable pulse generator (IPG), a charging system and a programmer. The IPG monitors the heart's activity and delivers non-excitatory electrical signals (cardiac contractility modulation therapy) to the right ventricle of the heart in patients with chronic heart failure. The charging system is used to recharge the IPG and the programmer to allow medical personnel to control the settings of the device. The Optimizer Smart IPG is implanted under the skin in the upper left or right area of the chest and connected to electrodes that attach to the heart. After implant, a doctor tests and programs the device based on the patient's individual requirements. The Optimizer Smart IPG monitors the heart's activity and delivers cardiac contractility modulation (CCM) therapy when the heart tissue is not capable of activation (myocardial absolute refactory period). As a result, CCM signals are non-excitatory and have no pacemaker or implantable defibrillator function. Instead, CCM signals triggers activities in heart muscle cells and improves cardiac performance." (FDA, 2019)

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))

1. 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**
2. 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**
3. 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 me**ets 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**)
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**)

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:

I25.5	Ischemic cardiomyopathy
I42.1, I42.2	Hypertrophic cardiomyopathy
I42.8	Other cardiomyopathies
I42.9	Cardiomyopathy, unspecified
I45.81	Long QT syndrome
I45.89	Other specified conduction disorders
I46.2 – I46.9	Cardiac arrest
I49.01	Ventricular fibrillation
I49.9	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.

Documentation Table	LOINC Codes	LOINC Time Frame Modifier Code	LOINC Time Frame Modifier Codes Narrative
Physician history and physical	28626-0	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.
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 Coverage Protocol Exemption Request

DEFINITIONS:

New York Heart Association (NYHA) Functional Classification:

NYHA Class	
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.

RELATED GUIDELINES:

Wearable and Non-Wearable Cardioverter-Defibrillators (WCD) for the Prevention of Sudden Cardiac Death, 01-93000-30

OTHER:

None applicable.

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COMMITTEE APPROVAL:

This Medical Coverage Guideline (MCG) was approved by the Florida Blue Medical Policy and Coverage Committee on 06/23/22.

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	Revision; Cardiac contractility modulation therapy position statement added; policy title, description, coding, and references updated.
04/01/22	Quarterly CPT/HCPCS Update. Code K1030 added.
07/15/22	Review: Position statements maintained; references updated.
10/01/22	Annual ICD-10 coding update. Code I47.2 deleted.
05/25/23	Update to Program Exceptions section.