Cardioverter Defibrillators/Cardiac Resynchronization Therapy

INDEPENDENT CARE HEALTH PLAN

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Medical Coverage Policy

Table of Contents

Related Medical/Pharmacy Coverage Policies

None

Related Documents

Please refer to CMS website for the most current applicable National Coverage Determination (NCD)/ Local Coverage Determination (LCD)/Local Coverage Article (LCA)/CMS Online Manual System/Transmittals.

Type	Title	ID Number	Jurisdiction Medicare	Applicable States/Territories

			Administrative Contractors (MACs)	
NCD	Implantable Cardioverter Defibrillators (ICDs)	20.4		
LCD (and pertinent LCA)	Cardiac Resynchronization Therapy (CRT)	L39080 A58821	JJ - Palmetto GBA (Part A/B MAC)	AL, GA, TN
LCD (and pertinent LCA)	Cardiac Resynchronization Therapy (CRT)	L39080 A58821	JM - Palmetto GBA (Part A/B MAC)	NC, SC, VA, WV
LCD (and pertinent LCA)	Automatic External Defibrillators	L33690 A52548	DME A - Noridian Healthcare Solutions, LLC (DME MAC) DME B - CGS Administrators, LLC (DME MAC) DME C - CGS Administrators, LLC (DME MAC) DME D - Noridian Healthcare Solutions, LLC (DME MAC)	All States

Description

Implantable Devices

The **implantable (transvenous) cardioverter defibrillator (ICD)** is an electronic device that continuously monitors heart rhythm and delivers therapy in response to a ventricular tachyarrhythmia that meets preprogrammed detection rates and duration in an individual who is at high risk of sudden cardiac death (SCD). If the heart develops a sudden life-threatening fast rhythm, the device will either deliver rapid electrical pacing pulses to terminate the arrhythmia or deliver a shock to the inside of the heart to stop the abnormal rhythm. Certain devices will also pace the heart when it beats too slowly. The devices are implanted in the subcutaneous tissue with one or more electrodes attached to the heart. Following implantation, an external interrogation (evaluation) may be performed periodically to ensure the defibrillator is working correctly.

An ICD may be indicated for use in an individual at risk for SCD due to hypertrophic cardiomyopathy (HCM), a condition in which the heart muscle thickens, making it more difficult to pump blood. Risk factors for SCD include, but may not be limited to one or more of the following:

- Personal history of cardiac arrest or sustained (greater than 30 seconds or associated with hemodynamic compromise) ventricular arrhythmias.
- Personal history of syncope suspected by clinical history to be arrhythmic.
- Family history in first- or second-degree relative of premature HCM-related sudden death, cardiac arrest or sustained ventricular arrhythmias.
- Cardiac imaging (echocardiography or coronary magnetic resonance [CMR]) determines maximal left ventricular (LV) wall thickness in all segments of the LV chamber, decreased ejection fraction (EF) or LV apical aneurysm.
- Diffuse and extensive late gadolinium enhancement (LGE), representing fibrosis, either quantified or estimated by visual inspection, comprising greater than 15% of LV mass.[11]
- Nonsustained (greater than or equal to 3 premature ventricular complexes terminating spontaneously) ventricular tachycardia (NSVT) episodes on continuous ambulatory electrocardiographic monitoring.[15]

Subcutaneous ICDs (S-ICD) are considered less invasive than transvenous ICDs as there are no leads placed in the heart or vasculature. Instead, an electrode is placed just beneath the skin of the chest which allows sensing of cardiac rhythms and delivery of shocks if necessary. The defibrillator can sense ventricular tachycardia (VT)/ventricular fibrillation (VF) but cannot provide prolonged antibradycardia and antitachycardia pacing.[44]

Cardiac resynchronization therapy (CRT) (also known as **biventricular pacing**) is used to treat some cases of advanced heart failure (HF). The CRT device provides electrical stimulation to both sides (left and right) of the heart thereby resynchronizing (coordinating) ventricular contractions. A third lead in the right atrium may also allow for synchronizing atrioventricular (AV) contractions. The device can be utilized with a defibrillator as a **cardiac resynchronization therapy/implantable cardioverter defibrillator (CRT-D)** or alone (without a defibrillator).

Ventricular dyssynchrony (uncoordinated contractions of the left and right ventricles) increases the risk of developing life-threatening arrhythmias. Implantation of a CRT-D allows for both coordinating ventricular contractions and terminating life-threatening arrhythmias.

Cardiac contractility modulation (CCM) is proposed to treat a symptomatic individual with HF who does not meet the criteria for CRT (eg, normal QRS duration). A pacemaker-sized device with electrodes is implanted into the chest of the individual which delivers electric pulses at regular intervals to modulate (adjust) the contractile strength of the heart muscle. Optimizer Smart is an example of a CCM device.

External Devices

Wearable cardioverter defibrillators (WCD) are vest-like devices that are worn under the clothing 24 hours a day except when bathing or showering. The device monitors and treats abnormal ventricular rhythms in an individual at risk of dying from sudden cardiac arrest (SCA). It consists of a garment with an electrode belt assembly that is worn around the chest next to the skin. This belt is connected to a monitor and alarm, which are worn around the waist. If a life-threatening rhythm is detected, an electric shock is delivered to restore normal rhythm. The ASSURE System and ZOLL LifeVest are examples of WCDs.

Automated external defibrillators (AEDs) are portable electronic devices that allow a minimally trained individual to provide electric shock to prevent death due to sudden cardiac arrest. These devices monitor heart rhythm and can, if needed, deliver an electric shock to the chest wall much like a traditional (paddle) defibrillator in a hospital.

Coverage Determination

iCare follows the CMS requirement that only allows coverage and payment for services that are reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member except as specifically allowed by Medicare.

In interpreting or supplementing the criteria above and in order to determine medical necessity consistently, iCare may consider the following criteria:

Automated External Defibrillators
Please refer to the above Medicare guidance for **automated external defibrillators**.

Implantable Cardioverter Defibrillators
Please refer to the above Medicare guidance for **implantable cardioverter defibrillators**.

Subcutaneous Implantable Defibrillators
An FDA-approved **subcutaneous implantable defibrillator (S-ICD)** will be considered medically reasonable and necessary when the following requirements are met:

- Criteria for an ICD are met;

AND EITHER of the following:

- High risk for bacteremia (eg, individual on hemodialysis or with chronic indwelling endovascular catheters); **OR**

- Limited vascular access;

AND absence of **ALL** the following**:**

- Requires pacing or CRT; **AND**

- Incessant VT or spontaneous, frequently recurring VT that is reliably terminated with antitachycardia pacing; **AND**

- Symptomatic bradycardia[74]

Replacement of S-ICDs: An individual with an existing S-ICD may receive an S-ICD replacement due to the end of battery life, ERI or device malfunction if the S-ICD continues to be medically necessary.

Wearable Cardioverter Defibrillators
Please refer to the above Medicare guidance for **wearable cardioverter defibrillators**.

Cardiac Resynchronization Therapy (CRT-P or CRT-D)
An FDA-approved **CRT or CRT-D** will be considered medically reasonable and necessary when the following requirements are met:

- NYHA Class III or (ambulatory) IV; **AND**
  - LVEF less than or equal to 35%; **AND**
    - Left bundle branch block (LBBB) with QRS duration greater than or equal to 120 milliseconds (ventricular dyssynchrony); **OR**
    - Non-LBBB with QRS duration greater than or equal to 150 milliseconds; **AND**
  - Sinus rhythm; **AND**
  - Remains symptomatic despite GDMT*; **OR**
- NYHA Class II; **AND**
  - LVEF less than or equal to 35%; **AND**
  - LBBB with QRS duration greater than or equal to 120 milliseconds (ventricular dyssynchrony); **AND**
  - Sinus rhythm; **AND**
  - Remains symptomatic despite GDMT*; **OR**
- NYHA Class II to (ambulatory) Class IV; **AND**
  - Nonobstructive HCM; **AND**
  - LBBB with QRS duration greater than or equal to 120 milliseconds; **AND**
  - LVEF less than 50%; **AND**
  - Sinus rhythm[15]; **OR**
- Atrial fibrillation; **AND**
  - AV nodal ablation or pharmacologic rate control will allow near 100% ventricular pacing with CRT; **AND**

- LVEF less than or equal to 35%; **AND**
- Remains symptomatic despite GDMT*****; **AND**
- Requires ventricular pacing or otherwise meets the above CRT criteria

Replacement of CRT or CRT-Ds: Individual with an existing CRT or CRT-D may receive a CRT or CRT-D replacement due to the end of battery life, ERI or device/lead malfunction if the CRT/CRT-D continues to be medically necessary.

***GDMT represents individualized optimal medical therapy for AF, HF and NICM and may include the following**:

- Aldosterone antagonists
- Angiotensin-converting enzyme inhibitors (ACEI)
- Angiotensin receptor blockers (ARB)
- Angiotensin receptor-neprilysin inhibitors (ARNI)[13]
- Anticoagulants
- Beta blockers
- Digoxin
- Diuretics
- Ivabradine[13]
- Nitrates[13]
- Sodium-glucose cotransporter-2 inhibitors (SLGT2i)[13]

The use of the criteria in this Medicare Advantage Medical Coverage Policy provides clinical benefits highly likely to outweigh any clinical harms. Services that do not meet the criteria above are not medically necessary and thus do not provide a clinical benefit. Medically unnecessary services carry risks of adverse outcomes and may interfere with the pursuit of other treatments which have demonstrated efficacy.

Coverage Limitations

US Government Publishing Office. Electronic code of federal regulations: part 411 – 42 CFR § 411.15 - Particular services excluded from coverage

Cardiac Resynchronization Therapy (CRT or CRT-D)
The following indications for **CRT or CRT-D** will not be considered medically reasonable and necessary:

- Individual with a QRS less than 130 ms (Exception to this non-coverage criterion would be in the case of an individual undergoing AV nodal ablation or in need of RV pacing [due to second- or third-degree block or very long first-degree block] that is expected to occur a majority of the time.)[33]; **OR**
- Individual with an EF greater than or equal to 50%[33]; **OR**

- CRT in an individual with nonambulatory NYHA IV HF symptoms or on chronic inotropic HF therapy or with LV assist device in place[33]

A review of the current medical literature shows that the evidence is insufficient to determine that these services are standard medical treatment. There remains an absence of randomized, blinded clinical studies examining benefit and long-term clinical outcomes establishing the value of these services in clinical management.

Cardiac Contractility Modulation (CCM)
Cardiac contractility modulation will not be considered medically reasonable and necessary.

A review of the current literature shows that the evidence is insufficient to determine that this service is standard medical treatment. There remains an absence of randomized, blinded clinical studies examining benefit and long-term outcomes establishing the value of this service in clinical management.

Summary of Evidence
Long-term study results comparing **CRT-D** therapy with ICD therapy alone for individuals with NYHA Class II and III heart failure symptoms and requiring an ICD showed a statistically significant risk reduction in mortality or heart failure events in the CRT-D group.[48] Individuals with a QRS less than 130 ms, an EF greater than 30% and nonambulatory NYHA IV HF symptoms were excluded from the randomized controlled trials (RCTs). Extension of benefit to individuals with narrow QRS has been attempted but generally failed and studies have shown no benefit to this group. Studies have shown no clinical benefit for those with normal ejection fraction or whose conditions or frailty (eg, nonambulatory NYHA IV) limit survival to less than one year.[13]

While clinical studies supported the US Food & Drug Administration (FDA) approval of the Optimizer Smart **cardiac contractility modulation system**, there continues to be a lack of RCTs with data supporting long-term clinical outcomes and associated complications.[66] An overall low-quality body of evidence suggests that CCM with the Optimizer Smart System as an adjunct to optimal medical therapy (OMT) may improve outcomes related to functional heart class severity and quality of life; however, uncertainty remains regarding clinical benefit versus OMT alone.[43] Independent, randomized, blinded comparative clinical studies are needed to determine whether CCM with the Optimizer Smart System is safe, more effective than OMT alone and has durable benefits.[45]

Coding Information

Any codes listed on this policy are for informational purposes only. Do not rely on the accuracy and inclusion of specific codes. Inclusion of a code does not guarantee coverage and/or reimbursement for a service or procedure.

CPT® Code(s)	Description	Comments
33206	Insertion of new or replacement of permanent pacemaker with transvenous electrode(s); atrial	

33207	Insertion of new or replacement of permanent pacemaker with transvenous electrode(s); ventricular	
33208	Insertion of new or replacement of permanent pacemaker with transvenous electrode(s); atrial and ventricular	
33214	Upgrade of implanted pacemaker system, conversion of single chamber system to dual chamber system (includes removal of previously placed pulse generator, testing of existing lead, insertion of new lead, insertion of new pulse generator)	
33215	Repositioning of previously implanted transvenous pacemaker or implantable defibrillator (right atrial or right ventricular) electrode	
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	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 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	
33234	Removal of transvenous pacemaker electrode(s); single lead system, atrial or ventricular	
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 implantable defibrillator pulse generator; single lead system	
33263	Removal of implantable defibrillator pulse generator with replacement of implantable defibrillator pulse generator; dual lead system	
33264	Removal of implantable defibrillator pulse generator with replacement of implantable 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	
33999	Unlisted procedure, cardiac surgery	
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	
93282	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; single lead transvenous implantable defibrillator system	

93283	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; dual lead transvenous implantable defibrillator system	
93284	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; multiple lead transvenous implantable defibrillator system	
93287	Peri-procedural device evaluation (in person) and programming of device system parameters before or after a surgery, procedure, or test with analysis, review and report by a physician or other qualified health care professional; single, dual, or multiple lead implantable defibrillator system	
93289	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; single, dual, or multiple lead transvenous implantable defibrillator system, including analysis of heart rhythm derived data elements	
93292	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; wearable defibrillator system	
93295	Interrogation device evaluation(s) (remote), up to 90 days; single, dual, or multiple lead implantable defibrillator system with interim analysis, review(s) and report(s) by a physician or other qualified health care professional	
93296	Interrogation device evaluation(s) (remote), up to 90 days; single, dual, or multiple lead pacemaker system, leadless pacemaker system, or implantable defibrillator system, remote data acquisition(s), receipt of transmissions and technician review, technical support and distribution of results	
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)	
93745	Initial set-up and programming by a physician or other qualified health care professional of wearable cardioverter-defibrillator includes initial programming of system, establishing baseline electronic ECG, transmission of data to data repository, patient instruction in wearing system and patient reporting of problems or events	
99457	Remote physiologic monitoring treatment management services, clinical staff/physician/other qualified health care professional time in a calendar month requiring interactive communication with the patient/caregiver during the month; first 20 minutes	
99458	Remote physiologic monitoring treatment management services, clinical staff/physician/other qualified health care professional time in a calendar month requiring interactive communication with the patient/caregiver during the month; each additional 20 minutes (List separately in addition to code for primary procedure)	
CPT® Category III Code(s)	**Description**	**Comments**
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	

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	
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	
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	
0412T	Removal of permanent cardiac contractility modulation system; pulse generator only	
0413T	Removal of permanent cardiac contractility modulation system; transvenous electrode (atrial or ventricular)	
0414T	Removal and replacement of permanent cardiac contractility modulation system pulse generator only	
0415T	Repositioning of previously implanted cardiac contractility modulation transvenous electrode, (atrial or ventricular lead)	
0416T	Relocation of skin pocket for implanted cardiac contractility modulation pulse generator	
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	
0418T	Interrogation device evaluation (in person) with analysis, review and report, includes connection, recording and disconnection per patient encounter, implantable cardiac contractility modulation system	
HCPCS Code(s)	**Description**	**Comments**
A9279	Monitoring feature/device, stand-alone or integrated, any type, includes all accessories, components and electronics, not otherwise classified	
C1721	Cardioverter-defibrillator, dual chamber (implantable)	
C1722	Cardioverter-defibrillator, single chamber (implantable)	
C1777	Lead, cardioverter-defibrillator, endocardial single coil (implantable)	
C1824	Generator, cardiac contractility modulation (implantable)	

C1882	Cardioverter-defibrillator, other than single or dual chamber (implantable)	
C1889	Implantable/insertable device, not otherwise classified	**Bundled**
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)	
C7537	Insertion of new or replacement of permanent pacemaker with atrial transvenous electrode(s), with 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)	
C7538	Insertion of new or replacement of permanent pacemaker with ventricular transvenous electrode(s), with 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)	
C7539	Insertion of new or replacement of permanent pacemaker with atrial and ventricular transvenous electrode(s), with 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)	
C7540	Removal of permanent pacemaker pulse generator with replacement of pacemaker pulse generator, dual lead system, with 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)	
E0617	External defibrillator with integrated electrocardiogram analysis	
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	
K0606	Automatic external defibrillator, with integrated electrocardiogram analysis, garment type	
K0607	Replacement battery for automated external defibrillator, garment type only, each	

K0608	Replacement garment for use with automated external defibrillator, each	
K0609	Replacement electrodes for use with automated external defibrillator, garment type only, each	
K1030	External recharging system for battery (internal) for use with implanted cardiac contractility modulation generator, replacement only	

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Appendix

Appendix A

Family Relationships

Family Relationship	Definition
First-degree	Child, full-sibling, parent
Second-degree	Aunt, uncle, grandparent, grandchild, niece, nephew, half-sibling
Third-degree	First cousin, great-aunt, great-grandchildren, great-grandparent, great-uncle, half-aunt, half-uncle

Appendix B

New York Heart Association (NYHA) Functional Classification System[13]

Classification	Symptoms
Class I (mild)	Individual with cardiac disease, but without resulting limitations on physical activity. Ordinary physical activity does not cause undue fatigue, palpitation, dyspnea or anginal pain.
Class II (mild)	Individual with cardiac disease resulting in slight limitations on physical activity. They are comfortable at rest. Ordinary physical activity results in fatigue, palpitation, dyspnea or anginal pain.
Class III (moderate)	Individual with cardiac disease resulting in marked limitations on physical activity. They are comfortable at rest. Less than ordinary activity causes fatigue, palpitation, dyspnea or anginal pain.
Class IV (severe)	Individual with cardiac disease resulting in inability to carry on any physical activity without discomfort. Symptoms of cardiac insufficiency or anginal syndrome may be present even at rest. If any physical activity is undertaken, discomfort increases.
Class IV (ambulatory)	Individual with class IV heart failure and no active acute coronary syndrome, no inotropes and on GDMT*[13]

Change Summary

- 01/01/2024 New Policy.