Implantable Cardioverter Defibrillators
Clinical Coverage Criteria

Overview

The implantable automatic defibrillator is an electronic device designed to detect and treat life-threatening tachyarrhythmias. The device consists of a pulse generator and electrodes for sensing and defibrillating. When the device senses an arrhythmia, it sends an electrical signal through the leads to terminate the arrhythmia and restore normal heart rhythm.

Policy

This Policy applies to the following Fallon Health products:

☒ Fallon Medicare Plus, Fallon Medicare Plus Central (Medicare Advantage)
☒ MassHealth ACO
☒ NaviCare HMO SNP (Dual Eligible Medicare Advantage and MassHealth)
☒ NaviCare SCO (MassHealth-only)
☒ PACE (Summit Eldercare PACE, Fallon Health Weinberg PACE)
☒ Community Care (Commercial/Exchange)

Prior authorization is required for insertion and/or replacement of implantable cardioverter defibrillators. This prior authorization is separate from any prior authorization that may be required for the member's inpatient hospital encounter.

Medicare Advantage
Fallon Health complies with CMS's national coverage determinations (NCDs), local coverage determinations (LCDs) of Medicare Contractors with jurisdiction for claims in the Plan's service area, and applicable Medicare statutes and regulations when making medical necessity determinations for Medicare Advantage members. When coverage criteria are not fully established in applicable Medicare statutes, regulations, NCDs or LCDs, Fallon Health may create internal coverage criteria under specific circumstances described at § 422.101(b)(6)(i) and (ii).

Medicare statutes and regulations do not have coverage criteria for implantable cardioverter defibrillators. Medicare has an NCD for Implantable Cardioverter Defibrillators (20.4), Version Number 5, Effective Date of this Version 07/31/2023. National Government Services, Inc., the Part A and B Medicare Administrative Contractor in the Plan's service area does not have an LCD for implantable cardioverter defibrillators (Medicare Coverage Database Search 08/25/2024).

Coverage criteria for implantable cardioverter defibrillators are fully established by Medicare, with the exception of patients who are candidates for heart transplantation on the United Network for Organ Sharing (UNOS) transplant list awaiting a donor heart. Coverage of ICDs, as with cardiac resynchronization therapy, as a bridge-to-transplant to prolong survival until a donor becomes available is determined by the Plan.

All other indications for ICDs not currently covered in accordance with this decision may be covered under Category B Investigational Device Exemption (IDE) trials (42 CFR 405.201).

Note: The coverage indications in NCD 20.4 apply to subcutaneous implantable cardioverter defibrillators (S-ICDs).

National Government Services, Inc. has a Billing and Coding Article: Implantable Automatic Defibrillators (A56326), Revision Effective Date 03/03/2023. Note: This Billing and Coding Article is not in direct support of an LCD.

Link: NCD **Implantable Cardioverter Defibrillators (20.4)**

Indications and Limitations of Coverage
B. Nationally Covered Indications

Effective for services performed on or after February 15, 2018 CMS has determined that the evidence is sufficient to conclude that the use of ICDs, (also referred to as defibrillators) is reasonable and necessary:

1. Patients with a personal history of sustained ventricular tachyarrhythmia (VT) or cardiac arrest due to ventricular fibrillation (VF). Patients must have demonstrated:
   - An episode of sustained VT, either spontaneous or induced by an electrophysiology (EP) study, not associated with an acute myocardial infarction (MI) and not due to a transient or reversible cause; or
   - An episode of cardiac arrest due to VF, not due to a transient or reversible cause.
2. Patients with a prior MI and a measured left ventricular ejection fraction (LVEF) ≤ 0.30. Patients must not have:
   - New York Heart Association (NYHA) classification IV heart failure; or,
   - Had a coronary artery bypass graft (CABG), or percutaneous coronary intervention (PCI) with angioplasty and/or stenting, within the past 3 months; or,
   - Had an MI within the past 40 days; or,
   - Clinical symptoms and findings that would make them a candidate for coronary revascularization.

   For these patients identified in B2, a formal shared decision making encounter must occur between the patient and a physician (as defined in Section 1861(r)(1) of the Social Security Act (the Act))or qualified non-physician practitioner (meaning a physician assistant, nurse practitioner, or clinical nurse specialist as defined in §1861(aa)(5) of the Act) using an evidence-based decision tool on ICDs prior to initial ICD implantation. The shared decision making encounter may occur at a separate visit.
3. Patients who have severe, ischemic, dilated cardiomyopathy but no personal history of sustained VT or cardiac arrest due to VF, and have NYHA Class II or III heart failure, LVEF ≤ 35%. Additionally, patients must not have:
   - Had a CABG, or PCI with angioplasty and/or stenting, within the past 3 months; or,
   - Had an MI within the past 40 days; or,
   - Clinical symptoms and findings that would make them a candidate for coronary revascularization.

   For these patients identified in B3, a formal shared decision making encounter must occur between the patient and a physician (as defined in Section 1861(r)(1) of the Act) or qualified nonphysician practitioner (meaning a physician assistant, nurse practitioner, or clinical nurse specialist as defined in §1861(aa)(5) of the Act) using an evidence-based decision tool on ICDs prior to initial ICD implantation. The shared decision making encounter may occur at a separate visit.
4. Patients who have severe, non-ischemic, dilated cardiomyopathy but no personal history of sustained VT or cardiac arrest due to VF, and have NYHA Class II or III heart failure, LVEF ≤ 35%, been on optimal medical therapy for at least 3 months. Additionally, patients must not have:
   - Had a CABG or PCI with angioplasty and/or stenting, within the past 3 months; or,
   - Had an MI within the past 40 days; or,

- Clinical symptoms and findings that would make them a candidate for coronary revascularization.

For these patients identified in B4, a formal shared decision making encounter must occur between the patient and a physician (as defined in Section 1861(r)(1) of the Act) or qualified nonphysician practitioner (meaning a physician assistant, nurse practitioner, or clinical nurse specialist as defined in §1861(aa)(5) of the Act) using an evidence-based decision tool on ICDs prior to initial ICD implantation. The shared decision making encounter may occur at a separate visit.

5. Patients with documented, familial or genetic disorders with a high risk of life-threatening tachyarrhythmias (sustained VT or VF), to include, but not limited to, long QT syndrome or hypertrophic cardiomyopathy.
   For these patients identified in B5, a formal shared decision making encounter must occur between the patient and a physician (as defined in Section 1861(r)(1) of the Act) or qualified nonphysician practitioner (meaning a physician assistant, nurse practitioner, or clinical nurse specialist as defined in §1861(aa)(5) of the Act) using an evidence-based decision tool on ICDs prior to initial ICD implantation. The shared decision making encounter may occur at a separate visit.
6. Patients with an existing ICD may receive an ICD replacement if it is required due to the end of battery life, elective replacement indicator (ERI), or device/lead malfunction.

For each of the 6 covered indications above, the following additional criteria must also be met:

1. Patients must be clinically stable (e.g., not in shock, from any etiology);
2. LVEF must be measured by echocardiography, radionuclide (nuclear medicine) imaging, cardiac magnetic resonance imaging (MRI), or catheter angiography;
3. Patients must not have:
   - Significant, irreversible brain damage; or,
   - Any disease, other than cardiac disease (e.g., cancer, renal failure, liver failure) associated with a likelihood of survival less than 1 year; or,
   - Supraventricular tachycardia such as atrial fibrillation with a poorly controlled ventricular rate.

Exceptions to waiting periods for patients that have had a CABG, or PCI with angioplasty and/or stenting, within the past 3 months, or had an MI within the past 40 days:

- Cardiac Pacemakers: Patients who meet all CMS coverage requirements for cardiac pacemakers, and who meet the criteria in this national coverage determination for an ICD, may receive the combined devices in one procedure, at the time the pacemaker is clinically indicated;
- Replacement of ICDs: Patients with an existing ICD may receive an ICD replacement if it is required due to the end of battery life, ERI, or device/lead malfunction.

C. Nationally Non-Covered Indications

N/A

D. Other

For patients that are candidates for heart transplantation on the United Network for Organ Sharing (UNOS) transplant list awaiting a donor heart, coverage of ICDs, as with cardiac resynchronization therapy, as a bridge-to-transplant to prolong survival until a donor becomes available, is determined by the local Medicare Administrative Contractors (MACs).

All other indications for ICDs not currently covered in accordance with this decision may be covered under Category B Investigational Device Exemption (IDE) trials (42 CFR 405.201).

MassHealth ACO
Fallon Health follows Medical Necessity Guidelines published by MassHealth when making medical necessity determinations for MassHealth members. In the absence of Medical Necessity Guidelines published by MassHealth, Fallon Health may create clinical coverage criteria in accordance with the definition of Medical Necessity in 130 CMR 450.204.

MassHealth does not have Guidelines for Medical Necessity Determination for implantable cardioverter defibrillators (MassHealth website search 08/25/2024), therefore, the Plan's coverage criteria are applicable.

NaviCare HMO SNP, NaviCare SCO
For plan members enrolled in NaviCare, Fallon Health first follow's CMS's national coverage determinations (NCDs), local coverage determinations (LCDs) of Medicare Contractors with jurisdiction for claims in the Plan's service area, and applicable Medicare statutes and regulations when making medical necessity determinations.

When coverage criteria are not fully established in applicable Medicare statutes, regulations, NCDs or LCDs, or if the NaviCare member does not meet coverage criteria in applicable Medicare statutes, regulations, NCDs or LCDs, Fallon Health then follows Medical Necessity Guidelines published by MassHealth when making necessity determinations for NaviCare members.

PACE (Summit Eldercare PACE, Fallon Health Weinberg PACE)
Each PACE plan member is assigned to an Interdisciplinary Team. PACE provides participants with all the care and services covered by Medicare and Medicaid, as authorized by the interdisciplinary team, as well as additional medically necessary care and services not covered by Medicare and Medicaid. With the exception of emergency care and out-of-area urgently needed care, all care and services provided to PACE plan members must be authorized by the interdisciplinary team.

Fallon Health Clinical Coverage Criteria

Effective for dates of service on or after September 1, 2024, Fallon Health will use InterQual® Criteria when making medical necessity determinations for implantable cardioverter defibrillators.

For coverage criteria, refer to the InterQual® Criteria in effect on the date of service:

- InterQual® CP:Procedures, Pacemaker Insertion, Biventricular + Implantable Cardioverter Defibrillator (ICD) Insertion
  These criteria cover biventricular pacemaker insertion with an implantable cardioverter defibrillator (ICD) or a pulse generator replacement. Criteria must be met for both the pacemaker and ICD insertion.
- InterQual® CP:Procedures, Implantable Cardioverter Defibrillator (ICD) Insertion
  These criteria cover single-chamber implantable cardioverter defibrillator (ICD) insertion, subcutaneous implantable cardioverter defibrillator insertion and pulse generator replacement. When a dual-chamber ICD insertion is planned, criteria must also be met for the insertion of an atrial pacing lead. For approval of the atrial pacing lead, see the "Pacemaker Insertion" criteria subset.
- InterQual® CP:Procedures, Pacemaker Insertion

Fallon Health makes InterQual® criteria available through the Transparency Tool on our website, effective January 1, 2024.

Medical necessity determination requires review of medical records. Specific elements of a member's medical records commonly required to establish medical necessity include recent clinical evaluation which includes a detailed history and physical examination; laboratory and imaging studies, procedure reports, and reports from other providers participating in the treatment of the relevant condition.

Exclusions

- Any use of implantable cardioverter defibrillators other than outlined above
- Extravascular implantable cardioverter defibrillator (0571T-0580T, 0614T)

Coding

The following codes are included below for informational purposes only; inclusion of a code does not constitute or imply coverage or reimbursement.

The CPT/HCPCS codes included below apply to implantable automatic defibrillators and subcutaneous implantable defibrillators.

HCPCS C codes C7537, C7538, C7539 and C7540 payable in ASC setting for providers reimbursed under Medicare ASC payment methodology.

Code	Description
33202	Insertion of epicardial electrode(s); open incision (eg, thoracotomy, median sternotomy, subxiphoid approach)
33203	Insertion of epicardial electrode(s); endoscopic approach (eg, thoracoscopy, pericardioscopy)
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
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
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)
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

Device C-codes

Code	Description
C1721	Cardioverter-defibrillator, dual chamber (implantable)
C1722	Cardioverter-defibrillator, single chamber (implantable)
C1777	Lead, cardioverter-defibrillator, endocardial single coil (implantable)
C1779	Lead, pacemaker, transvenous VDD single pass (implantable)
C1882	Cardioverter-defibrillator, other than single or dual chamber (implantable)
C1895	Lead, cardioverter-defibrillator, endocardial dual coil (implantable)
C1896	Lead, cardioverter-defibrillator, other than endocardial single or dual coil (implantable)
C1898	Lead, pacemaker, other than transvenous VDD single pass
C1899	Lead, pacemaker-cardioverter-defibrillator combination(implantable)

Extravascular Implantable Cardioverter Defibrillator

On December 4, 2019, CMS approved Medicare coverage for the Category B IDE study associated with the extravascular implantable cardioverter defibrillator (**G190186**); the Extravascular ICD Pivotal Study (EV ICD) sponsored by Medtronic, ClinicalTrials.gov ID **NCT04060680**. Category B IDE studies are covered by Fallon Health for Medicare Advantage

plan members only, including Fallon Medicare Plus and NaviCare HMO SNP (dual eligible Medicare/Medicaid).

The following codes are covered for Medicare Advantage plan members, including Fallon Medicare Plus and NaviCare HMO SNP (dual eligible Medicare/Medicaid), when the member is enrolled in Category B IDE study G190186 – Extravascular ICD Pivotal Study (EV ICD).

NCT04060680 is closed to enrollment and was completed on 04/04/2024.

Code	Description
0571T	Insertion or replacement of implantable cardioverter-defibrillator system with substernal electrode(s)
0572T	Insertion of substernal implantable defibrillator electrode
0573T	Removal of substernal implantable defibrillator electrode
0574T	Repositioning of previously implanted substernal implantable defibrillator pacing electrode
0575T	Programming device evaluation (in person) of implantable cardioverter defibrillator system with substernal electrode
0576T	Interrogation device evaluation (in person) of implantable cardioverter defibrillator system with substernal electrode
0577T	Electrophysiologic evaluation of implantable cardioverter defibrillator system with substernal electrode
0578T	Interrogation device evaluation(s) (remote), up to 90 days, substernal lead implantable cardioverter defibrillator system
0579T	Interrogation device evaluation(s) (remote), up to 90 days, substernal lead implantable cardioverter defibrillator system
0580T	Removal of substernal implantable defibrillator pulse generator only
0614T	Removal and replacement of substernal implantable defibrillator pulse generator

References

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Policy history

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Not all services mentioned in this policy are covered for all products or employer groups. Coverage is based upon the terms of a member's particular benefit plan which may contain its own specific provisions for coverage and exclusions regardless of medical necessity. Please consult the product's Evidence of Coverage for exclusions or other benefit limitations applicable to this service or supply. If there is any discrepancy between this policy and a member's benefit plan, the provisions of the benefit plan will govern. However, applicable state mandates take precedence with respect to fully-insured plans and self-funded non-ERISA (e.g., government, school boards, church) plans. Unless otherwise specifically excluded, federal mandates will apply to all plans.