



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.

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 MassHealth ACO and Community Care members 18 years of age and older.

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
Note: 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, Biventricular Implantable Cardioverter Defibrillator (ICD) Pulse Generator Replacement
- InterQual® CP:Procedures, Implantable Cardioverter Defibrillator (ICD) Insertion
Note: 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, Pulse Generator Replacement
- InterQual® CP:Procedures, Subcutaneous Implantable Cardioverter Defibrillator (SICD) Insertion
- InterQual® CP:Procedures, Pacemaker Insertion
- InterQual® CP:Procedures, Pacemaker Pulse Generator Replacement

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.

Medicare Variation

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 09/21/2025).

Coverage criteria for implantable cardioverter defibrillators are fully established by Medicare for beneficiaries who meet coverage criteria in section B. Nationally Covered Indications, under Indications and Limitations of Coverage.

For beneficiaries who are candidates for heart transplantation on the United Network for Organ Sharing (UNOS) transplant list awaiting a donor heart, coverage of implantable cardioverter defibrillators, as with cardiac resynchronization therapy, as a bridge-to-transplant to prolong survival until a donor becomes available will be 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) (Implantable Cardioverter Defibrillators CAG-00157R4).

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.

Medicare coverage is not available for extravascular implantable cardioverter-defibrillators for any indication when not part of a CMS-approved Category B Investigational Device Exemption (IDE) study (CMS Transmittal R4513CP). CMS-approved Category B IDE studies are listed at: <https://www.cms.gov/medicare/coverage/investigational-device-exemption-ide-studies/approved>.

MassHealth Variation

MassHealth does not have Guidelines for Medical Necessity Determination for implantable cardioverter defibrillators (MassHealth website search 09/21/2025), therefore, the Plan's coverage criteria are applicable.

Exclusions

- Any use of implantable cardioverter defibrillators other than outlined above.
- Extravascular implantable cardioverter defibrillator (EV-ICD) (CPT codes 0571T-0580T and 0614T), also known as substernal implantable cardioverter-defibrillators, are experimental/investigational and not medically necessary.

Summary of Evidence

Extravascular Implantable Cardioverter-Defibrillator

Implantable cardioverter defibrillators (ICDs) are established therapy for reducing the incidence of sudden cardiac death in at-risk populations. Traditional transvenous placement of an ICD lead can result in serious complications in both the short and long term, including vascular injury, venous obstructions, systemic infections, cardiac perforation, and complications during chronic lead extraction. The subcutaneous ICD (S-ICD) was introduced as an alternative to transvenous systems, placing the lead between the skin and the sternum. By avoiding the vasculature, the S-

ICD reduces the number and severity of complications compared with transvenous ICDs while effectively terminating ventricular arrhythmias. However, it does not provide antitachycardia pacing (ATP), and its location outside the chest wall necessitates a larger generator for higher energy shocks, which can affect battery longevity.

The extravascular ICD (EV ICD) was developed to provide the benefits of circumventing the vasculature while retaining many of the capabilities of a transvenous ICD system. Substernal lead placement of the EV ICD allows ATP and defibrillation therapy from a single device, with a size, projected longevity, and defibrillation threshold similar to those of transvenous systems while being outside the vasculature (Friedman et al., 2025).

Results from the first in-human pilot study, conducted in a small cohort of patients, showed that the EV ICD system could be safely implanted and could deliver effective defibrillation (Crozier et al., 2020). These findings were validated in the subsequent pivotal study in which the primary results exceeded safety and efficacy criteria in a large, global population through 6 months of follow-up ([Extravascular ICD Pivotal Study (EV ICD) ClinicalTrials.gov identifier: NCT04060680]).

EV ICD was a prospective, multi-center, single-arm, pre-market approval study, designed to enroll up to 400 patients at up to 60 sites. The purpose of this clinical study was to demonstrate the safety and efficacy of the EV-ICD System. The study was sponsored by Medtronic, with design and conduct oversight provided by a global steering committee of physicians. Patients with a class I or IIa indication for an ICD for primary or secondary prevention according to ACC/AHA/HRS (Al-Khabib et al., 2017) or ESC guidelines (Priori et al., 2015) were recruited. Patients who required bradycardia pacing or cardiac resynchronization therapy or who had undergone sternotomy were excluded. Results of EV-ICD are published by Friedman et al., 2022 and are also available in the FDA Summary of Safety and Effectiveness for the Aurora EV-ICD System (P22012B).

The primary efficacy end point was successful defibrillation at implantation, defined as termination of an induced sustained shockable ventricular arrhythmia either with one 20-J shock or with 30 J on two consecutive episodes. The efficacy objective would be met if the lower boundary of the one-sided 97.5% confidence interval for the percentage of patients with successful defibrillation was greater than 88% when testing was performed with a safety margin of 10 J or more. The primary safety end point was freedom from major system- or procedure-related complications at 6 months. The safety objective would be met if the lower boundary of the one-sided 97.5% confidence interval for the percentage of patients free from such complications was greater than 79%.

From September 2019 through October 2021, a total of 356 patients were enrolled at 46 centers in 17 countries across North America, Europe, Asia, and Oceania. Of these, 316 underwent an implantation attempt; 40 patients exited the study before an implantation attempt. Of the 316 subjects who underwent an implant attempt, 315 subjects had the lead positioned and proceeded to electrical testing during the implant procedure. In total, 299 (94.6%) had the EV-ICD System fully implanted and proceeded to long-term follow up.

Among subjects who completed the defibrillation testing protocol at implant, the proportion of those who had a defibrillation testing success was 98.7% (298/302). Of the successful defibrillation tests, conversion occurred with one 20J shock in 216 subjects, or approximately 73% of subjects; conversion was successful at 15J in 154 subjects, or approximately 50% of subjects. The 95% lower confidence bound of the successful conversion rate in 302 evaluable subjects was 96.6%. The primary efficacy objective was to demonstrate that the defibrillation efficacy at implant of the EV-ICD System exceeds 88%. Therefore, the study met its primary effectiveness objective.

Of the 316 subjects that underwent an implant attempt, 23 subjects had a total of 25 major EV-ICD System and/or procedure-related complications through 182 days post-implant. System modifications were performed 26 times across 25 subjects, or approximately 6% of subjects. After implant, 92 AEs in 70 subjects were adjudicated as serious and system related, including: Twenty-eight (28) events of inappropriate shock; Eleven (11) events of lead dislodgement; Eight

(8) events of chest pain; Five (5) events of medical device site pain. There were three (3) occurrences of lead fracture.

The Aurora EV-ICD™ System (Medtronic, Inc.) received FDA PMA approval (P22012) on October 20, 2023, based on the results of EV ICD.

In 2025, Friedman et al. reported the safety and efficacy of the EV ICD system through the extended follow-up of the pivotal study. Implantation attempt was successful in 299 patients, and those patients were followed up for an average of 30.6 ± 8.5 months. The first implantation occurred in September 2019, and the last patient exited the study in January 2024. All subjects were followed up for a minimum of 2 years, unless they exited before study closure for other reasons; the longest follow-up was 4.2 years after implantation, and one patient was lost to follow-up.

Through all of the follow-up, appropriate therapy was received by 24 patients for 82 spontaneous arrhythmic episodes, with 38 episodes (46.3%) receiving antitachycardia pacing (ATP) only, 34 (41.5%) receiving shock only, and 10 (12.2%) receiving both ATP and shock. There were 48 monomorphic VT episodes (n=14 patients) that received appropriate ATP therapy, with 37 episodes (n=9 patients) being successfully terminated by ATP for a success rate of 77.1%. ATP was nominally “off” in the device, and the proportion of patients who were reported to have ATP programmed “on” significantly increased from 66.8% at PHD to 81.2% at the last study visit ($P<0.0001$). At 2 years, ATP was programmed “off” in 2.8% of patients because of pacing sensation during in-clinic electrical testing; however, no patient that received successful ambulatory ATP subsequently had it programmed “off.”

A total of 31 major complications causally related to the EV ICD system or procedure occurred in 29 patients (9.2%), 6 (n=6 patients) of which occurred >6 months after implantation. The most common were lead dislodgement (10 events; n=9 patients, 2.8%), postoperative wound or implantation site infection (n=8, 2.5%), and device inappropriate shock delivery resulting in hospitalization (n=3, 0.9%) or system revision (n=1, 0.3%). Rate of freedom from major system- or procedure-related complications was 91.9% and 89.0% at one and 3 years, respectively. Three lead fractures occurred at 7, 11, and 34 months after implantation. All 3 were discovered through high-voltage lead impedance alerts. No inappropriate shocks occurred as a result of the fractures. No major intraprocedural complications, and no unique major complications related to the EV ICD system or procedure were reported. No deaths occurred from arrhythmia as a result of ineffective device therapy, and none occurred that had a causal relationship with the EV ICD system or procedure. In sudden cardiac death cases with a lack of information (eg, no device data, no autopsy) available for adjudication, events were conservatively adjudicated as possibly related to the system. Per this definition, 2 deaths were adjudicated as possibly related to the system.

A system revision was required in 24 patients (7.6%) because of a major complication related to the EV ICD system or procedure, 19 of which occurred within 1 year of implantation.

A system- or procedure-related infection was reported in 15 patients through the last follow-up, 13 occurring within 2 months of implantation (median occurrence, 0.9 months after implantation; minimum, 0.3 month; maximum, 24.2 months). Eight infections were classified as a major complication, 3 as a minor complication, and 4 as observations.

Inappropriate shocks were received by 46 patients for 135 episodes through all of follow-up. The Kaplan-Meier–estimated first inappropriate shock rate was 9.8% at 1 year and 17.5% at 3 years, with the majority of first inappropriate shocks observed within 6 months of implantation. The most common causes of inappropriate shock were P-wave oversensing (69 episodes), myopotential noise (35 episodes), and atrial fibrillation or atrial flutter (14 episodes). Inappropriate shocks were managed without system revision in 41 of 46 patients, of whom 30 of 41 (73.2%) did not receive a subsequent inappropriate shock after device interrogation through the final follow-up (mean, 19.0 ± 11.7 months of follow-up after interrogation). Five patients had a system revision after inappropriate shock (lead replaced), 4 in whom lead dislodgement was the primary cause and one with chronic myopotential oversensing.

The results of EV-ICD must be considered within the context of its limitations. The study was nonrandomized and single arm, with no comparator to subcutaneous or transvenous systems. Procedures were performed at expert centers in a clinical trial environment with a prespecified follow-up and testing protocol. Because the population in this study was younger than those who might typically receive an ICD, more data will be needed to evaluate the EV ICD performance in older patients with more comorbidities. These results display multiyear efficacy and safety, but assessing the EV ICD system over the lifetime of the device will be critical. This includes a more robust assessment of lead removal, device longevity, long-term complications, therapy rates, and lead stability over long (>4 years) time frames. The EV ICD system implanted during the pivotal study differs from the one currently being implanted because of the addition of an inappropriate shock reducing algorithm (Smart Sense) and manufacturing enhancements. In addition, implanter training has since been updated to focus on avoiding dislodgement and minimize P waves, so these results, inappropriate shocks in particular, may not be applicable to current experience (Friedman et al., 2025).

The Enlighten Study, a global, prospective registry, will evaluate the real-world safety and performance of the Aurora EV-ICD system with the Smart Sense algorithm over the lifetime of the device (ClinicalTrials.gov identifier: NCT06048731).

Analysis of Evidence (Rational for Determination)

A nonrandomized and single arm study, with no comparator to subcutaneous or transvenous systems demonstrated that an extravascular ICD system terminated spontaneous ventricular arrhythmias with a high rate of antitachycardia pacing (ATP) and defibrillation therapy success and a low major complication rate through 2 years follow-up. Longer-term data showing generalizability and population representativeness to the real-world population are needed.

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 (EV-ICD)

Medicare coverage is not available for extravascular implantable cardioverter-defibrillators for any indication when not part of a CMS-approved Category B Investigational Device Exemption (IDE) study (CMS Transmittal R4513CP). CMS-approved Category B IDE studies are listed at: <https://www.cms.gov/medicare/coverage/investigational-device-exemption-ide-studies/approved>.

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 were covered for Medicare Advantage plan members, including Fallon Medicare Plus and NaviCare HMO SNP (dual eligible Medicare/Medicaid), for members 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

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Policy history

Origination date: 09/01/2018
Review/Approval(s): Technology Assessment Committee: 08/22/2018 (adopted as new criteria), 09/10/2019 (updated references), 02/10/2022 (Added clarifying language related to Medicare Advantage, NaviCare and PACE under Policy section; updated coding), 08/27/2024 (annual review, updated Medicare Advantage and MassHealth ACO language in Policy section, adopted InterQual® Criteria effective 09/01/2024, updated Coding section and References), 09/23/2025 (annual review, updated formatting to include new sections for Medicare and MassHealth Variation, no changes to coverage criteria).
Utilization Management Committee: 10/21/2025 (annual review, approved with no changes to coverage criteria).

Instructions for Use

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).

Fallon Health generally 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.

For plan members enrolled in NaviCare, Fallon Health first follows 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.

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.

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.

