



Subcutaneous Implantable Defibrillators Clinical Coverage Criteria

Overview

An implantable defibrillator is a device designed to treat and diagnose life-threatening ventricular tachyarrhythmias. The implantable defibrillator consists of a pulse generator and electrodes for sensing and defibrillating. Studies and trials have shown these devices improve survival and reduce sudden cardiac death in patients with certain clinical symptoms and diagnoses.

A subcutaneous implantable defibrillator is considered to be a less invasive alternative to a traditional transvenous implantable cardioverter defibrillator as there are no leads placed in the heart or vasculature. Instead, an electrode is placed beneath the skin of the chest this allows the sensing of cardiac rhythms and delivery of shocks if necessary.

Policy

This Policy applies to the following Fallon Health products:

- Commercial
- Medicare Advantage
- MassHealth ACO
- NaviCare
- PACE

Fallon Health follows guidance from the Centers for Medicare and Medicaid Services (CMS) for organization (coverage) determinations for Medicare Advantage plan members. National Coverage Determinations (NCDs), Local Coverage Determinations (LCDs), Local Coverage Articles (LCAs) and guidance in the Medicare manuals are the basis for coverage determinations. When there is no NCD, LCD, LCA or manual guidance, Fallon Health Clinical Coverage Criteria are used for coverage determinations.

Medicare has an NCD for Implantable Automatic Defibrillators (20.4). National Government Services, Inc. does not have an LCD for implantable automatic defibrillators. National Government Services, Inc. has an LCA: Billing and Coding: Implantable Automatic Defibrillators (A56326) (MCD search 02/10/2022).

For plan members enrolled in NaviCare, Fallon Health follows Medicare guidance for coverage determinations. In the event that there is no Medicare guidance or if the plan member does not meet medical necessity criteria in Medicare guidance, Fallon Health Clinical Coverage Criteria are used for coverage determinations for NaviCare members. Fallon Health's Clinical Coverage Criteria are developed in accordance with the definition of Medical Necessity in 130 CMR 450.204.

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 requires prior authorization for subcutaneous implantable defibrillators.

Fallon Health Clinical Coverage Criteria

Fallon health considers subcutaneous implantable defibrillators medically necessary when the following criteria are met as supported by the treating provider(s) medical records:

The member must have a medical need for a standard defibrillator and not have any of the following conditions:

- Symptomatic bradycardia
- Incessant ventricular tachycardia (VT)
- Spontaneous frequent recurring VT reliably terminated with anti-tachycardia pacing

Additionally coverage will be considered for members who have had previous endocarditis or infection associated with conventional implantable cardioverter-defibrillators.

Medicare members: Fallon Health follows Medicare coverage criteria for requests for subcutaneous implantable defibrillators for Medicare plan members including Medicare Advantage, NaviCare and PACE plan members.

NCD link: [Implantable Automatic Defibrillators \(20.4\)](#)

LCA link: [Billing and Coding: Implantable Automatic Defibrillators \(A56326\)](#)

Exclusions

- Any use of subcutaneous implantable defibrillators other than outlined above.

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.

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
G0448	Insertion or replacement of a permanent pacing cardioverterdefibrillator system with transvenous lead(s), single or dual chamber with insertion of pacing electrode, cardiac venous system, for left ventricular pacing

References

1. CMS National Coverage Determination for Implantable Automatic Defibrillators (20.4). Effective October 1, 2003.
2. National Government Services, Inc. Local Coverage Article: Billing and Coding: Implantable Automatic Defibrillators (A56326). Original Effective Date 03/26/2019. Revision Effective Date 05/07/2020. Available at: <https://www.cms.gov/medicare-coverage-database/new-search/search.aspx>. Accessed 02/10/2022.
3. Hayes Inc. Hayes Brief: Subcutaneous Implantable Cardioverter Defibrillator (S-ICD) for Prevention of Sudden Cardiac Death. Published March 30, 2017. Annual review completed April 25, 2019.
4. Alpert JS, Thygesen K, Antman E, Bassand JP. Myocardial infarction redefined--a consensus document of The Joint European Society of Cardiology/American College of Cardiology Committee for the redefinition of myocardial infarction. *J Am Coll Cardiol.* 2000 Sep;36(3):959-69.
5. Sakhi R, Yap SC, Michels M, Schinkel AFL, et. al. Evaluation of a novel automatic screening tool for determining eligibility for a subcutaneous implantable cardioverter-defibrillator. *Int J Cardiol.* 2018 Dec 1;272:97-101.
6. Garside H, Leyva F, Hudsmith L, Marshall H, de Bono J. Eligibility for subcutaneous implantable cardioverter defibrillators in the adult congenital heart disease population. *Pacing Clin Electrophysiol.* 2019 Jan;42(1):65-70.

Policy history

Origination date: 09/01/2018
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).

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.