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**Kaiser Foundation Health Plan of Washington**

# *Clinical Review Criteria*
# Cardiac Defibrillators

- Implantable Cardioverter Defibrillator (ICD)
- Subcutaneous implantable Cardioverter Defibrillator (SICD)
- Substernal implantable Cardioverter Defibrillator



## Criteria

### For Medicare Members

| Source | Policy |
|---|---|
| CMS Coverage Manuals | Medicare Claims Processing Manual, Change Request 11605 – Transmittal 4513, section 19: ***Extravascular Implantable Cardioverter Defibrillator (EV ICD)*** **Covered if performed as part of an approved Investigational Device Exemption (IDE) study* |
| National Coverage Determinations (NCD) | Implantable Cardioverter Defibrillator (ICD) requires Level of Care review ***AND*** medical necessity review against NCD Implantable Cardioverter Defibrillators (ICD) (20.4) |
| Local Coverage Determinations (LCD) | None |
| Local Coverage Article | Implantable Cardioverter Defibrillator (ICD) requires requires Level of Care review ***AND*** medical necessity review Billing and Coding: Implantable Automatic Defibrillators (A56342) |

### For Non-Medicare Members

| Service | Criteria |
|---|---|
| **Subcutaneous Implantable Cardioverter Defibrillator (SICD)** | The use of the SICD may be considered medically necessary for all appropriate pacemaker patients who meet the following criteria:<br><br>A. Have a contraindication to a transvenous ICD due to at least **ONE of the following**:<br>1. Lack of adequate vascular access; or<br>2. The need to preserve existing vascular access due to chronic dialysis; or<br>3. Repeat transvenous ICD placement not indicated due to complications with previous transvenous ICD placement; or<br>4. Congenital heart disease; or<br>5. Increased risk for bacteremia<br><br>The use of the SICD is considered investigational when the |


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| | above criteria are not met. |
| **Substernal Implantable Cardioverter Defibrillator** | The use of a substernal ICD (CPT Codes 0571T-0580T, 0614T) is considered investigational. |
| **Implantable Cardioverter Defibrillator (ICD)** | Requires Level of Care review ***AND*** medical necessity review. Kaiser Permanente has elected to use coverage guidance from Medicare's National Coverage Determination (NCD) Implantable Cardioverter Defibrillators (ICD) (20.4) |

The following information was used in the development of this document and is provided as background only. It is provided for historical purposes and does not necessarily reflect the most current published literature. When significant new articles are published that impact treatment option, Kaiser Permanente will review as needed. This information is not to be used as coverage criteria. Please only refer to the criteria listed above for coverage determinations.

## Background

Cardiovascular disease is the most common cause of death in the Western world, and sudden cardiac death (SCD) accounts for approximately 60% of all cardiovascular mortality. SCD is responsible for ~300,000 annual deaths in the United States; with ventricular fibrillation (VF) accounting for up to one-third of cases (Zipes 1998, Estes 2011, Majithia 2014, Rhyner 2014).

The implantable cardioverter defibrillator (ICD) was developed and introduced to clinical practice around the 1980s to address this issue of fatal SCD from ventricular tachyarrhythmia. The ICD continuously monitors the heart, identifies malignant ventricular tachyarrhythmia, and delivers an electric counter shock to restore normal rhythm. The first defibrillator received FDA approval in 1985 to be used in patients who had survived cardiac arrests. In 2002, the FDA expanded its use to patients with a history of a heart attack and depressed heart function. ICDs are widely used and studies have shown significant mortality benefit in selected patients at increased risk of SCD. However, the use of ICDs may at times be complicated with the implantation procedure, programing, device malfunction, and lead performance deterioration by time. Traditionally, the ICD is implanted transvenously by creating a pocket in the subclavicular areas and gaining vascular access to reach the heart. This approach has its drawbacks and is associated with short- and long-term adverse events. Reported complications associated with ICD systems include lead dislodgement, lead fracture, conductor coil breaks, pneumothorax, cardiac perforation, pericardial effusion, cardiac tamponade, and systemic infection. Lead malfunction occurs in up to 40% of the transvenous leads at 8 years after implantation. Lead failure either generates inappropriate shocks or impedes appropriate therapy. Extraction of the lead is recommended in cases of lead fracture, malfunction, or other mechanical problems that prevent safe and effective ICD shock therapies. This extraction is complex and can be associated with significant risks including death (Olde Nordkamp 2012, Weiss 2013, Aziz 2014, Chang 2014Majithia 2014).

The complications associated with the intracardiac leads of the implantable cardioverter defibrillators have led to the development of a totally subcutaneous ICD (S-ICD) with the intention to provide the same protection, but with less procedural and device-related risks. The S-ICD system senses, detects, and treats malignant ventricular tachycardia (VT)/ventricular fibrillation (VF) without requiring vascular access or fluoroscopy. The S-ICD system (model SQ-RX 1010, Cameron Health, Inc., San Clemente, CA) includes a dedicated external programmer, a subcutaneous pulse generator enclosed in a titanium case, and a single subcutaneous electrode containing both sensing and defibrillating components. The lead-electrode is composed of proximal and distal sensing electrodes separated by a shocking coil. The pulse generator is implanted in a subcutaneous pocket created over the fifth intercostal space between the mid and anterior axillary lines. The single lead is tunneled from the xiphoid process to the pocket and to the sternal manubrium joint. Fixation is achieved with the addition of a suture sleeve at the level of the xiphoid and a single suture at the superior parasternal portion of the lead. Implantation of the device relies entirely on anatomic landmarks and does not require fluoroscopy (although some investigators advocate brief screening to verify the final position). The currently used pulse generator weighs 145 g, has a volume of 69 ml, and an estimated 5-year battery life. The greatest advantage of S-ICD is that the lead does not pass through the central veins in the chest, nor is it attached to the tissue within the heart chambers. However, the pulse generator of the S-ICD is approximately twice the volume and weight of the currently used transvenous ICD, which may prevent its use in children, and increase the risk of erosion, discomfort, and infection. In addition, the


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weight of the device may cause its dislodgement and changes in the shock configuration (Olde Nordkamp 2012, Weiss 2013, Aziz 2014, Chang 2014, Grace 2014, Majithia 2014).

The S-ICD system detects changes in the ventricular rate by using subsurface electrocardiography through a primary, secondary, or alternate vector. The device is programmed to select the vector that best avoids double QRS counting or T-wave oversensing events that could lead to misinterpretation of the rhythm and delivery of inappropriate shock. The heart rate is measured as the average of 4 consecutive sensed intervals. VF is diagnosed when 18 of 24 consecutive sensed events exceed the shock zone limit. Once the system detects a malignant arrhythmia, it delivers up to 80 J shock to terminate the arrhythmia and will automatically reverse polarity if the initial shock fails to terminate the arrhythmia. The mean defibrillation threshold is significantly higher than with transvenous devices, and some investigators suggest that high-energy shocks may be harmful to the myocardium (Aziz 2014, Majithia 2014, Nair 2014).

Unlike the conventional ICD devices, S-ICD is unable to provide long-term bradycardia pacing or antitachycardia pacing due to the absence of an endocardial lead. It is thus not suitable for patients with an indication for antibradycardia pacing or cardiac resynchronization therapy, or for those with a history of repetitive monomorphic ventricular tachycardia that would benefit from antitachycardia pacing. S-ICD may not be used concurrently with unipolar pacemaker as that would interfere with the S-ICD arrhythmia detection. This absence of bradycardia pacing in the S-ICD might lead to more bradycardia related events as syncope or even death. The device may be potentially useful for patients who are not eligible for transvenous ICDs, or are at high risk of complications e.g. subjects with congenital heart disease, complicated vascular anatomy, at high risk of infection, or in patients in whom vascular access is limited or needs to be conserved e.g. for renal dialysis or long-term intravenous drug therapy (Akerstrom 2013, Olde Nordkamp 2012, Chang 2014, Majithia 204).

S-ICD received US FDA approval in September 2012, “To provide defibrillation therapy for the treatment of life-threatening ventricular tachyarrhythmia in patients who do not have sympathetic bradycardia, incessant (continual) ventricular tachycardia, or spontaneous frequently recurring ventricular tachycardia that is reliably terminated with anti-tachycardia Pacing”. The FDA required that a post-approval registry be created to track outcomes of patients and devices for at least 60 months after implantation.

S-ICD has not been previously reviewed by MTAC; it is being reviewed based on a request for the Clinical Review Unit for coverage decision.

## Medical Technology Assessment Committee (MTAC)

***Subcutaneous Implantable Cardioverter Defibrillator***

**10/20/2014: MTAC REVIEW**

**Evidence Conclusion:** The results of the published observational studies suggest that S-ICD may be accurate in detecting and reversing induced ventricular arrhythmias, however, the incidence of inappropriate therapy was as high as 13.1% (in a mean duration of 11 months in Weiss et al 2013). Inappropriate shock therapy may decrease the quality of life and increase the mortality risk.

The published studies evaluated the accuracy, efficacy and safety of S-ICD in reversing induced rather than spontaneous arrhythmias. The arrhythmia is not always predictable and as seen in one study (Kobe 2013) the S-ICD system had to be changed to transvenous ICD in a patient who needed antitachycardia pacing (ATP) therapy. A group of investigators (Gold and colleague 2012) noted that though there is no reason to suspect that electograms may differ between induced and spontaneous rhythms of similar rates and regularity, this possibility of this difference cannot be excluded. *Conclusion:* The results of the published literature indicate that: There is some evidence that S-ICD may be accurate in detecting and reversing induced ventricular arrhythmias. There is insufficient evidence to date, to determine the efficacy or effectiveness to S-ICD in terminating spontaneous VT/VF episodes. S-ICD may lead to inappropriate shock therapy in up to 13.1% of cases. There is insufficient evidence to determine the long-term safety of the S-ICD system. There is insufficient evidence to determine that S-ICD is safer or more effective than conventional transvenous ICD. No randomized controlled trial that compared the two devices head to head was published to date. There is insufficient evidence to determine that the use of S-ICD prevents or reduces sudden death from ventricular arrhythmias.

**Articles**: The literature search revealed over 300 citations on subcutaneous implantable cardioverter defibrillator. The majority were reviews or opinion pieces. No published RCTs that compared the safety and efficacy of the S-ICD head to head with the conventional transvenous ICD or other therapeutic interventions were identified; only the published rationale and design of the ongoing PRAETORIAN trial that is comparing the subcutaneous to the transvenous implantable defibrillators. There were a number of published observational studies including those that led to the European approval as well as the pivotal study (Weiss et al, 2013) leading to the US Food and

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Drug Administration approval. The search also identified a paper documenting the early results from the EFFORTLESS S-ICD Registry that was created to document the clinical, system, and patient-related outcome data from patients implanted with S-ICD in multiple centers in Europe and New Zealand. The pivotal prospective study (Weiss et al, 2013) and a study with a comparison group (Kobe 2013) were selected for critical appraisal: Weiss R, Knight BP, Gold MR, et al. Safety and efficacy of a totally subcutaneous implantable-cardioverter defibrillator. Circulation. 2013; 128(9):944-953. See Evidence Table. Köbe J, Reinke F, Meyer C, et al. Implantation and follow-up of totally subcutaneous versus conventional implantable cardioverter-defibrillators: a multicenter case-control study. Heart Rhythm. 2013;10 (1):29-36. See Evidence Table.

The use of Subcutaneous Implantable Cardioverter Defibrillator does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

## References

Centers for Medicare & Medicaid Services (CMS) [website]. Medicare Coverage Database. National Coverage Determinations (NCDs). Updated January 3, 2008. Available at: http://www.cms.hhs.gov/mcd/index_list.asp?list_type=ncd. Accessed November 07, 2023.

## Applicable Codes

**Subcutaneous ICD (SICD)**
**Considered Medically Necessary when criteria in the applicable policy statements listed above are met:**

| CPT® or HCPC Codes | Description |
|---|---|
| **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 |
| **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 |
| **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) |

**Substernal ICD**

**Medicare - Considered medically necessary when performed as part of an approved Investigative Device Exemption (IDE) study:**
**Non-Medicare – Considered not medically necessary - experimental, investigational or unproven:**

| CPT® or HCPC Codes | Description |
|---|---|
| **0571T** | Insertion or replacement of implantable cardioverter-defibrillator system with substernal electrode(s), including all imaging guidance and electrophysiological evaluation (includes defibrillation threshold evaluation, induction of arrhythmia, evaluation of sensing for arrhythmia termination, and programming or reprogramming of sensing or therapeutic parameters), when performed |
| **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 |

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| | substernal electrode, 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 |
| **0576T** | Interrogation device evaluation (in person) of implantable cardioverter-defibrillator system with substernal electrode, with analysis, review and report by a physician or other qualified health care professional, includes connection, recording and disconnection per patient encounter |
| **0577T** | Electrophysiologic evaluation of implantable cardioverter-defibrillator system with substernal electrode (includes defibrillation threshold evaluation, induction of arrhythmia, evaluation of sensing for arrhythmia termination, and programming or reprogramming of sensing or therapeutic parameters |
| **0578T** | Interrogation device evaluation(s) (remote), up to 90 days, substernal lead implantable cardioverter-defibrillator system with interim analysis, review(s) and report(s) by a physician or other qualified health care professional |
| **0579T** | Interrogation device evaluation(s) (remote), up to 90 days, substernal lead implantable cardioverter-defibrillator system, remote data acquisition(s), receipt of transmissions and technician review, technical support and distribution of results |
| **0580T** | Removal of substernal implantable defibrillator pulse generator only |
| **0614T** | Removal and replacement of substernal implantable defibrillator pulse generator |

**Implantable Cardioverter Defibrillators**

**Considered medically necessary when criteria in the applicable policy statements listed above are met:**

| CPT® or HCPC Codes | Description |
|---|---|
| **33216** | Insertion of a single transvenous electrode, permanent pacemaker or implantable defibrillator |
| **33217** | Insertion of 2 transvenous electrodes, permanent pacemaker or implantable defibrillator |
| **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 |
| **33249** | Insertion or replacement of permanent implantable defibrillator system, with transvenous lead(s), single or dual chamber |
| **C1721** | Cardioverter-defibrillator, dual chamber (implantable) |
| **C1722** | Cardioverter-defibrillator, single chamber (implantable) |
| **C1882** | Cardioverter-defibrillator, other than single or dual chamber (implantable) |
| **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 |

***Note:** Codes may not be all-inclusive. Deleted codes and codes not in effect at the time of service may not be covered.

****To verify authorization requirements for a specific code by plan type, please use the **Pre-authorization Code Check**.



| Date Created | Date Reviewed | Date Last Revised |
|---|---|---|
| 10/23/2014 | 11/04/2014 MPC, 09/01/2015MPC, 07/05/2016MPC, 05/02/2017MPC, 03/06/2018MPC, 03/05/2019MPC, 03/03/2020MPC, 03/02/2021MPC, 03/01/2022MPC , 03/07/2023MPC | 11/07/2023 |

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| Revision History | Description |
|---|---|
| 07/18/2016 | Added NCD 20.4 |
| 09/08/2015 | Revised LCD L35008 |
| 11/07/2017 | MPC approved to adopt criteria for SICD |
| 03/01/2022 | Added Medicare links and codes related to subcutaneous ICD, noted that substernal ICD is considered investigational for non-Medicare. |
| 11/07/2023 | MPC approved adopting Medicare coverage criteria of Defibrillator and Pacemaker placement for commercial members and gold card WPMG Cardiology subject to ongoing audits of compliance with the stated criteria. |



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