Medical Necessity Guidelines:

Subcutaneous Implantable Cardioverter Defibrillator (S-ICD)

Effective: January 1, 2025

Prior Authorization Required If REQUIRED, submit supporting clinical documentation pertinent to service request to the FAX numbers below	Yes ☐ No ☒
Prior Authorization Required If REQUIRED, concurrent review may apply	Yes ☐ No ☒

Applies to:

Commercial Products

☒ Harvard Pilgrim Health Care Commercial products; 800-232-0816

☒ Tufts Health Plan Commercial products; 617-972-9409

CareLink℠ – Refer to CareLink Procedures, Services and Items Requiring Prior Authorization

Public Plans Products

☒ Tufts Health Direct – A Massachusetts Qualified Health Plan (QHP) (a commercial product); 888-415-9055

☒ Tufts Health Together – MassHealth MCO Plan and Accountable Care Partnership Plans; 888-415-9055

☒ Tufts Health RITogether – A Rhode Island Medicaid Plan; 857-304-6404

☒ Tufts Health One Care – A dual-eligible product; 857-304-6304

Senior Products

☐ Harvard Pilgrim Health Care Stride Medicare Advantage; 866-874-0857

☐ Tufts Health Plan Senior Care Options (SCO), (a dual-eligible product); 617-673-0965

☐ Tufts Medicare Preferred HMO, (a Medicare Advantage product); 617-673-0965

☐ Tufts Medicare Preferred PPO, (a Medicare Advantage product); 617-673-0965

Note: While you may not be the provider responsible for obtaining prior authorization or notifying Point32Health, as a condition of payment you will need to ensure that any necessary prior authorization has been obtained and/or Point32Health has received proper notification. If notification is required, providers may additionally be required to provide updated clinical information to qualify for continued service.

Overview

Sudden cardiac death (SCD) is an unanticipated, sudden death caused by loss of heart function that occurs within one hour of the onset of acute symptoms. Sudden cardiac death causes about 325,000 adult deaths annually in the U.S. and is thought to account for 50-60% of all cardiovascular deaths. The majority of SCDs are believed to be caused by ventricular fibrillation or ventricular tachycardia, which are irregular heart rhythms brought about when the electrical system to the heart malfunctions. Implantable cardioverter-defibrillators (ICDs) can reduce the risk of sudden cardiac arrest and sudden cardiac death associated with dangerous arrhythmias by detecting these irregular rhythms when they occur and delivering an electrical shock to the heart muscle to cause the heart to beat in a normal rhythm again. Conventional transvenous ICDs (TV-ICDs) have leads (wires) lying within the right ventricle. The risks of placing these devices include pneumothorax, pericardial effusion, tamponade, infection, and thrombosis. The S-ICD system does not require transvenous insertion; instead, the system electrode in placed under the skin and implanted outside of the rib cage. The S-ICD system includes an implantable lead, an implantable pulse generator, a lead insertion tool, and a programming device that communicates wirelessly with the pulse generator.

Clinical Guideline Coverage Criteria

The Plan may cover a subcutaneous implantable cardioverter defibrillator (S-ICD) for Members who require an implantable cardioverter-defibrillator to reduce the risk of sudden cardiac arrest and sudden cardiac death, and who meet **ONE** of the

following:

1. History of infection or endocarditis associated with a conventional implantable cardioverter defibrillator device: **or**
2. The provider has determined that the Member is at high risk for thoracotomy or transvenous lead placement (e.g. risk of lead complication, high infection risk, those with venous access issues).

Limitations

1. The Plan will not cover a subcutaneous implantable cardioverter defibrillator for Members who have symptomatic bradycardia or continual (incessant) ventricular tachycardia that can be terminated with anti-tachycardia pacing, and/or patients who have unipolar pacemakers.

Codes

The following code(s) are associated with this service:

Table 1: HCPCS Codes

CPT® 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
33272	Removal of subcutaneous implantable defibrillator electrode
33273	Repositioning of previously implanted subcutaneous implantable defibrillator electrode

References:

1. Hayes Inc. Hayes Health Technology Brief. S-ICD (Subcutaneous Implantable Cardiovert Defibrillator; Boston Scientific Corp.) for prevention of sudden cardiac death. December 6, 2013. Lansdale, PA: Hayes, Inc.; updated October 24, 2022.
2. U.S. Food and Drug Administration (FDA). Subcutaneous Implantable Defibrillator (S-ICD) System - P110042. Device Approvals and Clearances. Silver Spring, MD: FDA; updated May 11, 2022.
3. Zipes DP, Camm AJ, Borggrefe M, et al. ACC/AHA/ESC 2006 guidelines for management of patients with ventricular arrhythmias and the prevention of sudden cardiac death: a report of the American College of Cardiology/American Heart Association Task Force and the European Society of Cardiology Committee for Practice Guidelines (Writing Committee to Develop Guidelines for Management of Patients With Ventricular Arrhythmias and the Prevention of Sudden Cardiac Death). J Am Coll Cardiol 2006;48:e247–e346.
4. Boston Scientific Corp. How the S-ICD System Works. Available at sicdsystem.com. Accessed August 24, 2022.
1. Cleveland Clinic, Sudden Cardiac Death (Sudden Cardiac Arrest). Available at my.clevelandclinic.org/services/heart/disorders/arrhythmia/sudden-cardiac-death. Updated May, 2015. Accessed October 6, 2022
2. Baddour LM, Esquer Garrigos Z, Sohail MR, et al. Update on Cardiovascular Implantable Electronic Device Infections and Their Prevention, Diagnosis, and Management: A Scientific Statement From the American Heart Association. Circulation. 2023;147(10):e1187-e1234. doi:10.1161/CIR.0000000000001187
3. Karchmer AW, Chu VH, Montgomery JA. Infections involving cardiac implantable electronic devices: Epidemiology, microbiology, clinical manifestations, and diagnosis. UpToDate. 2024. Accessed November 7, 2024. https://www.uptodate.com/contents/infections-involving-cardiac-implantable-electronic-devices-epidemiology-microbiology-clinical-manifestations-and-diagnosis.
4. Pun PH, Parzynski CS, Friedman DJ, Sanders G, Curtis JP, Al-Khatib SM. Trends in Use and In-Hospital Outcomes of Subcutaneous Implantable Cardioverter Defibrillators in Patients Undergoing Long-Term Dialysis. *Clin J Am Soc Nephrol*. 2020;15(11):1622-1630. doi:10.2215/CJN.07920520

Approval And Revision History

November 16, 2022: Reviewed by the Medical Policy Approval Committee (MPAC) for integration between Harvard Pilgrim Health Care and Tufts Health Plan

Subsequent endorsement date(s) and changes made:

- November 16, 2023: Reviewed by MPAC, renewed without changes

- November 2023: Unify name changed to OneCare effective January 1, 2024
- December 1, 2023: Reviewed and approved by the UM Committee
- November 21, 2024: Reviewed by MPAC. Clarified criterion #2 to include “e.g. risk of lead complication, high infection risk, those with venous access issues”. Effective January 1, 2025
- December 13, 2024: Reviewed and approved by the UM Committee, effective January 1, 2025

Background, Product and Disclaimer Information

Medical Necessity Guidelines are developed to determine coverage for benefits and are published to provide a better understanding of the basis upon which coverage decisions are made. We make coverage decisions using these guidelines, along with the Member’s benefit document, and in coordination with the Member’s physician(s) on a case-by-case basis considering the individual Member's health care needs.

Medical Necessity Guidelines are developed for selected therapeutic or diagnostic services found to be safe and proven effective in a limited, defined population of patients or clinical circumstances. They include concise clinical coverage criteria based on current literature review, consultation with practicing physicians in our service area who are medical experts in the particular field, FDA and other government agency policies, and standards adopted by national accreditation organizations. We revise and update Medical Necessity Guidelines annually, or more frequently if new evidence becomes available that suggests needed revisions.

For self-insured plans, coverage may vary depending on the terms of the benefit document. If a discrepancy exists between a Medical Necessity Guideline and a self-insured Member’s benefit document, the provisions of the benefit document will govern. For Tufts Health Together (Medicaid), coverage may be available beyond these guidelines for pediatric members under age 21 under the Early and Periodic Screening, Diagnostic and Treatment (EPSDT) benefits of the plan in accordance with 130 CMR 450.140 and 130 CMR 447.000, and with prior authorization.

Treating providers are solely responsible for the medical advice and treatment of Members. The use of this guideline is not a guarantee of payment or a final prediction of how specific claim(s) will be adjudicated. Claims payment is subject to eligibility and benefits on the date of service, coordination of benefits, referral/authorization, utilization management guidelines when applicable, and adherence to plan policies, plan procedures, and claims editing logic.