Medical Necessity Guidelines:
Subcutaneous Implantable Cardioverter Defibrillator (S-ICD)

Effective: November 18, 2020

Prior Authorization Required If REQUIRED, submit supporting clinical documentation pertinent to service request.	**Yes ☐ No ☒**

Applies to:
COMMERCIAL Products
☒Tufts Health Plan Commercial products; Fax: 617.972.9409
☒Tufts Health Freedom Plan products; Fax: 617.972.9409
- CareLink℠ – Refer to CareLink Procedures, Services and Items Requiring Prior Authorization

TUFTS HEALTH PUBLIC PLANS Products
☒Tufts Health Direct – A Massachusetts Qualified Health Plan (QHP) (a commercial product); Fax:888.415.9055
☒Tufts Health Together – MassHealth MCO Plan and Accountable Care Partnership Plans; Fax: 888.415.9055
☒Tufts Health RITogether – A Rhode Island Medicaid Plan; Fax: 857.304.6404
☒Tufts Health Unify* – OneCare Plan (a dual-eligible product); Fax: 857.304.6304
*The MNG applies to Tufts Health Unify members unless a less restrictive LCD or NCD exists.

SENIOR Products
- Tufts Health Plan Senior Care Options (SCO), (a dual-eligible product) – Refer to the Tufts Health Plan SCO Prior Authorization List
- Tufts Medicare Preferred HMO, (a Medicare Advantage product) – Refer to the Tufts Medicare Preferred HMO Prior Authorization and Inpatient Notification List

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 COVERAGE CRITERIA

Tufts Health 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 criteria:
- History of infection or endocarditis associated with a conventional implantable cardioverter-defibrillator device
- The Member's provider has deemed him or her an unacceptable risk for thoracotomy/ transvenous lead placement

LIMITATIONS

- Tufts Health 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

Covered CPT Codes

CPT Code	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, 2015.
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, 2015.
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, 2015.
5. 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, 2015.

APPROVAL HISTORY

October 14, 2015: Reviewed by the Integrated Medical Policy Advisory Committee for an effective date of January 1, 2016

Subsequent endorsement date(s) and changes made:

- December 9, 2015: Reviewed by IMPAC, renewed without changes
- December 14, 2016: Reviewed by IMPAC, renewed without changes
- April 2017: Added RITogether Plan product to template. For MNGs applicable to RITogether, effective date is August 1, 2017
- December 13, 2017: Reviewed by IMPAC, renewed without changes
- October, 2018: Template and disclaimer updated
- November 14, 2018: Reviewed by IMPAC, renewed without changes
- November 20, 2019: Reviewed by IMPAC, renewed without changes
- November 18, 2020: Reviewed by IMPAC, renewed without changes
- December 8, 2020: Fax number for Unify updated

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.

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.

Provider Services