Sentara Health Plans

Commercial

Transvenous Implantable Cardioverter Defibrillator

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Effective Date	7/2023
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Member-specific benefits take precedence over medical policy and benefits may vary across plans. Refer to the individual's benefit plan for details *.

Purpose:

This policy addresses the medical necessity of Transvenous Implantable cardioverter defibrillator (ICD).

Description & Definitions:

Transvenous Implantable cardioverter defibrillator (ICD) is a battery-powered electronic device with a generator which is implanted under the skin with attached lead wires inserted through the vessels to the inside of the heart, which deliver an electric pulse or shock to help restore a normal heartbeat.

Criteria:

Transvenous Implantable Cardioverter Defibrillator is considered medically necessary with **all of the** following:

- Individual has cardiac condition that requires Transvenous Implantable Cardioverter-Defibrillator (ICD) placement as indicated by **1 or more** of the following:
  - **Ischemic cardiomyopathy** (known coronary artery disease) and **1 or more** of the following:
    - New York Heart Association class I heart failure with left ventricular ejection fraction less than or equal to 30%
    - New York Heart Association class II or III heart failure with left ventricular ejection fraction less than or equal to 35%
    - Syncope presumed to be due to ventricular arrhythmia and inducible sustained (lasting 30 seconds or more) ventricular tachycardia
    - Left ventricular ejection fraction less than 40% and **ALL** of the following:
      - Nonsustained ventricular tachycardia
      - Inducible sustained ventricular tachycardia
    - Sustained (lasting 30 seconds or more) or hemodynamically significant (eg, Hypotension) ventricular tachycardia not believed to be due to reversible etiology (eg, myocardial ischemia, severe electrolyte abnormality)
  - **Nonischemic cardiomyopathy** and **1 or more** of the following:
    - Syncope presumed to be due to ventricular tachycardia

        - Stable ventricular tachycardia not due to reversible causes
        - Induced or spontaneous ventricular tachycardia that is hemodynamically significant (eg, Hypotension) or sustained (lasting 30 seconds or longer)
        - New York Heart Association class I to III heart failure and **ALL of** the following:
            - Left ventricular ejection fraction less than or equal to 35%
            - Individual treated for at least 3 months with guideline-directed medical therapy
            - Survival is reasonably expected to be greater than 1 year
        - New York Heart Association class IV heart failure and **1 or more** of the following:
            - Heart transplant candidate
            - Left ventricular assist device candidate or implanted
            - Candidate for cardiac resynchronization therapy (ie, device will incorporate both pacing and defibrillation capabilities)
        - History of Chagas disease
        - History of myotonic dystrophy
        - History of heart failure due to amyloidosis
        - History of giant cell myocarditis
        - Peripartum cardiomyopathy persisting more than 3 months post partum
    - **Cardiac arrest** due to ventricular fibrillation or ventricular tachycardia without known treatable precipitating cause (eg, myocardial ischemia, electrolyte disorder, myocarditis)
    - **Sustained (lasting 30 seconds or longer) ventricular tachycardia** and left ventricular ejection fraction less than or equal to 35%
    - **Child with sustained ventricular tachycardia** inadequately controlled with medication or catheter ablation, and with no evidence of incessant ventricular tachyarrhythmias
    - **Ventricular fibrillation** or polymorphic ventricular tachycardia within 48 hours of MI and **1 or more** of the following:
        - Revascularization of infarct vessel not feasible
        - Inducible sustained ventricular tachycardia or ventricular fibrillation at electrophysiologic study performed 4 or more days after revascularization
    - **Individual within 40 days of Myocardial Infarction** (MI) and **1 or more** of the following:
        - Syncope presumed to be due to ventricular arrhythmia and inducible sustained (lasting 30 seconds or more) ventricular tachycardia
        - New York Heart Association class I heart failure with **ALL** of the following:
            - Left ventricular ejection fraction less than or equal to 30%
            - Recovery of left ventricular function not expected
            - Individual having permanent pacemaker placed
        - New York Heart Association class II or III heart failure with **ALL** of the following:
            - Left ventricular ejection fraction less than or equal to 35%
            - Recovery of left ventricular function not expected
            - Individual having permanent pacemaker placed
        - Left ventricular ejection fraction less than 40% and **ALL of** the following:
            - Nonsustained ventricular tachycardia
            - Inducible sustained ventricular tachycardia
        - New York Heart Association class IV heart failure with **ALL of** the following:
            - Individual is ambulatory (not bed bound)
            - Individual is a candidate for cardiac transplant, left ventricular assist device, or cardiac resynchronization therapy
    - **Individual who has been revascularized** (with bypass surgery or percutaneous intervention) within last 90 days and is not within 40 days of acute MI with **1 or more** of the following:
        - Individual requires permanent pacemaker and **ALL of** the following:
            - Left ventricular ejection fraction less than or equal to 35%
            - Recovery of left ventricular ejection fraction not expected

        - Syncope presumed to be due to ventricular arrhythmia and inducible sustained (lasting 30 seconds or more) ventricular tachycardia
        - Left ventricular ejection fraction less than 40% and **ALL of** the following:
            - Nonsustained ventricular tachycardia
            - Inducible sustained ventricular tachycardia
        - Sustained (lasting 30 seconds or more) or hemodynamically significant (eg, Hypotension) ventricular tachycardia not believed to be due to reversible etiology (eg, myocardial ischemia, severe electrolyte abnormality)
    - **Individual with history of MI** (more than 40 days ago, not revascularized in last 90 days) and **1 or more** of the following:
        - Sustained (lasting 30 seconds or more) or hemodynamically significant (eg, Hypotension) ventricular tachycardia not believed to be due to reversible etiology (eg, myocardial ischemia, severe electrolyte abnormality)
        - Syncope presumed to be due to ventricular arrhythmia and inducible sustained (lasting 30 seconds or more) ventricular tachycardia
        - New York Heart Association class I heart failure with left ventricular ejection fraction less than or equal to 30%
        - New York Heart Association class II or III heart failure with left ventricular ejection fraction less than or equal to 35%
        - Left ventricular ejection fraction less than 40% and **ALL of** the following:
            - Nonsustained ventricular tachycardia
            - Inducible sustained ventricular tachycardia
        - Left ventricular ejection fraction less than or equal to 40%, and patient having permanent pacemaker placed
    - **Syncope** presumed to be due to ventricular arrhythmia with **1 or more** of the following:
        - Inducible sustained ventricular tachycardia
        - Left ventricular ejection fraction less than or equal to 35%
        - Cardiac amyloidosis
        - Arrhythmogenic right ventricular dysplasia or cardiomyopathy
        - Hypertrophic obstructive cardiomyopathy
        - Advanced structural heart disease (eg, valvular heart disease, congenital heart disease)
    - **Individual has genetic condition** that increases risk of sudden cardiac death as indicated by **1 or more** of the following:
        - Long QT syndrome and **1 or more** of the following:
            - History of cardiac arrest (eg, resuscitated ventricular fibrillation)
            - Corrected QT interval greater than 500 milliseconds while receiving beta-blocker
            - Adult in whom beta-blocker therapy is ineffective (eg, persistent symptoms) or not tolerated
            - Child with symptomatic ventricular arrhythmia in whom beta-blocker therapy is ineffective or not tolerated and alternative therapies (eg, cardiac sympathetic denervation, alternative antiarrhythmic agents) are ineffective or inappropriate
            - Syncope presumed to be due to ventricular arrhythmia
            - Genotypes LQT2 or LQT3
            - Female with genotype LQT2
        - Arrhythmogenic right ventricular dysplasia or cardiomyopathy and **1 or more** of the following:
            - Sustained (lasting 30 seconds or longer) or hemodynamically significant (eg, Hypotension) ventricular tachycardia
            - Right or left ventricular ejection fraction less than or equal to 35%
            - Syncope presumed to be due to ventricular arrhythmia
            - Risk factors for sudden cardiac death indicated by **1 or more** of the following:
                - Frequent premature ventricular contractions

- Family history of premature sudden death
- Inducible ventricular tachycardia

- Brugada syndrome and **1 or more** of the following:
  - Patient has spontaneous type 1 Brugada syndrome ECG pattern and **1 or more of the following:**
    - Sustained (lasting 30 seconds or longer) or hemodynamically significant (eg, Hypotension)[D] ventricular tachycardia
    - Inducible sustained (lasting 30 seconds or more) ventricular tachycardia
    - History of cardiac arrest (eg, resuscitated ventricular fibrillation)
    - Syncope presumed to be due to ventricular arrhythmia[B]
  - Individual with other than spontaneous type 1 Brugada syndrome ECG pattern with response to pharmacologic challenge (eg, procainamide, flecainide, ajmaline), as indicated by **1 or more** of the following:
    - Ventricular arrhythmia
    - Marked QRS widening
    - Type 1 Brugada syndrome ECG pattern
- Catecholaminergic polymorphic ventricular tachycardia and **1 or more** of the following:
  - Adult with sustained (lasting 30 seconds or more) ventricular tachycardia while receiving beta-blocker therapy
  - Adult with syncope presumed to be due to a ventricular arrhythmia[B] while receiving beta-blocker therapy
  - Child with arrhythmic syncope, or polymorphic/bidirectional ventricular tachycardia despite alternative treatment (eg, beta-blocker, flecainide, cardiac sympathetic denervation)
- Hypertrophic cardiomyopathy and **1 or more** of the following:
  - Previous documented cardiac arrest
  - Sustained ventricular tachycardia (lasting longer than 30 seconds)
  - History of sudden death attributed to hypertrophic cardiomyopathy in first-degree or second-degree relative 50 years of age or younger
  - Left ventricular hypertrophy 30 mm or greater in any segment
  - Nonsustained ventricular tachycardia (eg, identified on ambulatory monitoring)
  - Syncope suspected to be due to arrhythmia
  - Left ventricular ejection fraction less than 50%
  - Late gadolinium enhancement on cardiac MRI
  - Adult individual with left ventricular apical aneurysm
- Short QT syndrome[L](1)(28)
- Noncompaction of left ventricle[M](29)(30)
- Lamin A/C mutation and **2 or more** of the following:
  - Male sex
  - Left ventricular ejection fraction less than or equal to 45%
  - Nonsustained ventricular tachycardia
- Lamin A/C mutation and indication for permanent pacemaker is present
- Phospholamban cardiomyopathy and **1 or more** of the following:
  - Left ventricular ejection fraction of less than 45%
  - Nonsustained ventricular tachycardia
- Filamin-C cardiomyopathy and left ventricular ejection fraction of less than 45%
- Other familial cardiomyopathy associated with sudden death

- **Cardiac sarcoidosis** and **1 or more** of the following:
  - Ventricular tachycardia that is hemodynamically significant (eg, Hypotension)[D] or sustained (lasting 30 seconds or longer)

        - Left ventricular ejection fraction less than or equal to 35% after treatment with optimal medical therapy for heart failure and immunosuppression (if active inflammation is present)
        - Left ventricular ejection fraction of 36% to 49% and right ventricular ejection fraction less than 40% despite treatment with optimal medical therapy for heart failure and immunosuppression (if active inflammation is present)
        - Evidence of myocardial scar by cardiac MRI or PET scan
        - Permanent pacemaker required
        - Syncope presumably due to ventricular arrhythmia[B]
        - Inducible sustained ventricular arrhythmia
    - **Congenital heart disease** and **1 or more** of the following
        - Sustained (lasting 30 seconds or longer) or hemodynamically significant ventricular tachycardia without identified reversible etiology (eg, myocardial ischemia, severe electrolyte abnormality)
        - Inducible sustained (lasting 30 seconds or longer) ventricular tachycardia
        - Single ventricle or systemic right ventricle with ejection fraction less than or equal to 35%
        - Left ventricular ejection fraction 35% or less
        - Awaiting heart transplant
        - Syncope presumably due to ventricular arrhythmia
        - Tetralogy of Fallot and **1 or more** of the following:
            - Left ventricular systolic or diastolic dysfunction
            - QRS duration of 180 milliseconds or more
            - QRS fragmentation (eg, multiple notched R waves)
            - Right ventricular scarring
            - Inducible sustained ventricular tachycardia
            - Other risk for sudden cardiac death (eg, impaired systolic or diastolic function, nonsustained ventricular tachycardia)
    - **Left ventricular assist device** with ventricular tachycardia that is sustained (lasting longer than 30 seconds)
    - **Post heart transplant** and **ALL of** the following:
        - Left ventricular dysfunction
        - Severe allograft vasculopathy
    - **Individual without contraindication to ICD placement** as indicated by **ALL of** the following:
        - No condition limiting life expectancy to less than 1 year (eg, advanced malignancy)
        - No treatment-refractory class IV heart failure in individual who is not candidate for cardiac transplant or left ventricular assist device
        - No significant psychiatric illness that may be aggravated by device implantation or that may preclude regular follow-up
        - No ongoing IV drug abuse
        - No unresolved infection associated with risk for hematogenous seeding
        - No history of significant nonadherence with medical therapy and follow-up

Transvenous Implantable cardioverter defibrillator (ICD) is considered **not medically necessary** for any use other than those indicated in clinical criteria.

Coding:

Medically necessary with criteria:

Coding	Description
33216	Insertion of a single transvenous electrode, permanent pacemaker or implantable defibrillator

33217	Insertion of 2 transvenous electrodes, permanent pacemaker or implantable defibrillator
33249	Insertion or replacement of permanent implantable defibrillator system, with transvenous lead(s), single or dual chamber

Considered Not Medically Necessary:

Coding	Description
	None

U.S. Food and Drug Administration (FDA) - approved only products only.

Document History:

Revised Dates:
Reviewed Dates:
Effective Date:

- July 2023

References:

Specialty Association Guidelines; Government Regulations; Winifred S. Hayes, Inc; UpToDate; Literature Review; Specialty Advisors; National Coverage Determination (NCD); Local Coverage Determination (LCD).

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Special Notes: *

Medical policies can be highly technical and complex and are provided here for informational purposes. These medical policies are intended for use by health care professionals. The medical policies do not constitute medical advice or medical care. Treating health care professionals are solely responsible for diagnosis, treatment, and medical advice. Sentara Health Plan members should discuss the information in the medical policies with their treating health care professionals. Medical technology is constantly evolving, and these medical policies are subject to change without notice, although Sentara Health Plan will notify providers as required in advance of changes that could have a negative impact on benefits.

Services mean both medical and behavioral health (mental health) services and supplies unless We specifically tell You otherwise. We do not cover any services that are not listed in the Covered Services section unless required to be covered under state or federal laws and regulations. We do not cover any services that are not Medically Necessary. We sometimes give examples of specific services that are not covered but that does not mean that other similar services are covered. Some services are covered only if We authorize them. When We say You or Your We mean You and any of Your family members covered under the Plan. Call Member Services if You have questions.

Keywords:

SHP Transvenous Implantable Cardioverter Defibrillator, SHP Surgical 133, cardiac arrest, ventricular fibrillation, ventricular tachycardia, polymorphic ventricular tachycardia, syncope, New York Heart Association, Ischemic cardiomyopathy, heart failure, Arrhythmogenic right ventricular dysplasia, cardiomyopathy, Brugada syndrome, revascularized, ejection fraction, pacemaker, Cardiac sarcoidosis, congenital heart disease, Chagas disease, myotonic dystrophy, amyloidosis, giant cell myocarditis, Peripartum cardiomyopathy