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Status: Revised
Doc ID: CAR06-0324.1
Effective Date: 03/17/2024
Last Review Date: 09/07/2023

Approval and implementation dates for specific health plans may vary. Please consult the applicable health plan for more details.

Clinical Appropriateness Guidelines

Cardiovascular

Appropriate Use Criteria: Implantable Cardioverter Defibrillators

Proprietary

Table of Contents

Description and Application of the Guidelines

The Carelon Clinical Appropriateness Guidelines (hereinafter “the Carelon Clinical Appropriateness Guidelines” or the “Guidelines”) are designed to assist providers in making the most appropriate treatment decision for a specific clinical condition for an individual. The Guidelines establish objective and evidence-based criteria for medical necessity determinations, where possible, that can be used in support of the following:

- To establish criteria for when services are medically necessary
- To assist the practitioner as an educational tool
- To encourage standardization of medical practice patterns
- To curtail the performance of inappropriate and/or duplicate services
- To address patient safety concerns
- To enhance the quality of health care
- To promote the most efficient and cost-effective use of services

The Carelon guideline development process complies with applicable accreditation and legal standards, including the requirement that the Guidelines be developed with involvement from appropriate providers with current clinical expertise relevant to the Guidelines under review and be based on the most up-to-date clinical principles and best practices. Resources reviewed include widely used treatment guidelines, randomized controlled trials or prospective cohort studies, and large systematic reviews or meta-analyses. Carelon reviews all of its Guidelines at least annually.

Carelon makes its Guidelines publicly available on its website. Copies of the Guidelines are also available upon oral or written request. Additional details, such as summaries of evidence, a list of the sources of evidence, and an explanation of the rationale that supports the adoption of the Guidelines, are included in each guideline document.

Although the Guidelines are publicly available, Carelon considers the Guidelines to be important, proprietary information of Carelon, which cannot be sold, assigned, leased, licensed, reproduced or distributed without the written consent of Carelon.

Carelon applies objective and evidence-based criteria, and takes individual circumstances and the local delivery system into account when determining the medical appropriateness of health care services. The Carelon Guidelines are just guidelines for the provision of specialty health services. These criteria are designed to guide both providers and reviewers to the most appropriate services based on a patient’s unique circumstances. In all cases, clinical judgment consistent with the standards of good medical practice should be used when applying the Guidelines. Guideline determinations are made based on the information provided at the time of the request. It is expected that medical necessity decisions may change as new information is provided or based on unique aspects of the patient’s condition. The treating clinician has final authority and responsibility for treatment decisions regarding the care of the patient and for justifying and demonstrating the existence of medical necessity for the requested service. The Guidelines are not a substitute for the experience and judgment of a physician or other health care professionals. Any clinician seeking to apply or consult the Guidelines is expected to use independent medical judgment in the context of individual clinical circumstances to determine any patient’s care or treatment.

The Guidelines do not address coverage, benefit or other plan specific issues. Applicable federal and state coverage mandates take precedence over these clinical guidelines, and in the case of reviews for Medicare Advantage Plans, the Guidelines are only applied where there are not fully established CMS criteria. If requested by a health plan, Carelon will review requests based on health plan medical policy/guidelines in lieu of the Carelon Guidelines. Pharmaceuticals, radiotracers, or medical devices used in any of the diagnostic or therapeutic interventions listed in the Guidelines must be FDA approved or conditionally approved for the intended use. However, use of an FDA approved or conditionally approved product does not constitute medical necessity or guarantee reimbursement by the respective health plan.

The Guidelines may also be used by the health plan or by Carelon for purposes of provider education, or to review the medical necessity of services by any provider who has been notified of the need for medical necessity review, due to billing practices or claims that are not consistent with other providers in terms of frequency or some other manner.

General Clinical Guideline

Clinical Appropriateness Framework

Critical to any finding of clinical appropriateness under the guidelines for a specific diagnostic or therapeutic intervention are the following elements:

- Prior to any intervention, it is essential that the clinician confirm the diagnosis or establish its pretest likelihood based on a complete evaluation of the patient. This includes a history and physical examination and, where applicable, a review of relevant laboratory studies, diagnostic testing, and response to prior therapeutic intervention.
- The anticipated benefit of the recommended intervention is likely to outweigh any potential harms, including from delay or decreased access to services that may result (net benefit).
- Widely used treatment guidelines and/or current clinical literature and/or standards of medical practice should support that the recommended intervention offers the greatest net benefit among competing alternatives.
- There exists a reasonable likelihood that the intervention will change management and/or lead to an improved outcome for the patient.

Providers may be required to submit clinical documentation in support of a request for services. Such documentation must a) accurately reflect the clinical situation at the time of the requested service, and b) sufficiently document the ordering provider's clinical intent.

If these elements are not established with respect to a given request, the determination of appropriateness will most likely require a peer-to-peer conversation to understand the individual and unique facts that would justify a finding of clinical appropriateness. During the peer-to-peer conversation, factors such as patient acuity and setting of service may also be taken into account to the extent permitted by law.

Simultaneous Ordering of Multiple Diagnostic or Therapeutic Interventions

Requests for multiple diagnostic or therapeutic interventions at the same time will often require a peer-to-peer conversation to understand the individual circumstances that support the medical necessity of performing all interventions simultaneously. This is based on the fact that appropriateness of additional intervention is often dependent on the outcome of the initial intervention.

Additionally, either of the following may apply:

- Current literature and/or standards of medical practice support that one of the requested diagnostic or therapeutic interventions is more appropriate in the clinical situation presented; or
- One of the diagnostic or therapeutic interventions requested is more likely to improve patient outcomes based on current literature and/or standards of medical practice.

Repeat Diagnostic Intervention

In general, repeated testing of the same anatomic location for the same indication should be limited to evaluation following an intervention, or when there is a change in clinical status such that additional testing is required to determine next steps in management. At times, it may be necessary to repeat a test using different techniques or protocols to clarify a finding or result of the original study.

Repeated testing for the same indication using the same or similar technology may be subject to additional review or require peer-to-peer conversation in the following scenarios:

- Repeated diagnostic testing at the same facility due to technical issues
- Repeated diagnostic testing requested at a different facility due to provider preference or quality concerns

- Repeated diagnostic testing of the same anatomic area based on persistent symptoms with no clinical change, treatment, or intervention since the previous study
- Repeated diagnostic testing of the same anatomic area by different providers for the same member over a short period of time

Repeat Therapeutic Intervention

In general, repeated therapeutic intervention in the same anatomic area is considered appropriate when the prior intervention proved effective or beneficial and the expected duration of relief has lapsed. A repeat intervention requested prior to the expected duration of relief is not appropriate unless it can be confirmed that the prior intervention was never administered. Requests for on-going services may depend on completion of previously authorized services in situations where a patient's response to authorized services is relevant to a determination of clinical appropriateness.

Implantable Cardioverter Defibrillators

Codes

The following code list is not meant to be all-inclusive. Authorization requirements will vary by health plan. Please consult the applicable health plan for guidance on specific procedure codes.

Specific CPT codes for services should be used when available. Nonspecific or not otherwise classified codes may be subject to additional documentation requirements and review.

CPT/HCPCS

00534	Anesthesia for transvenous insertion or replacement of pacing cardioverter-defibrillator
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
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
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 pacing cardioverter-defibrillator pulse generator with replacement of pacing cardioverter-defibrillator pulse generator; single lead system
33263	Removal of pacing cardioverter-defibrillator pulse generator with replacement of pacing cardioverter-defibrillator pulse generator; dual lead system
33264	Removal of pacing cardioverter-defibrillator pulse generator with replacement of pacing cardioverter-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
93640	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
93641	Removal of implantable defibrillator pulse generator only
C1721	Cardioverter-defibrillator, dual chamber (implantable)
C1722	Cardioverter-defibrillator, single chamber (implantable)
C1777	Lead, cardioverter-defibrillator, endocardial single coil (implantable)

C1882	Cardioverter-defibrillator, other than single or dual chamber (implantable)
C1895	Lead, cardioverter-defibrillator, endocardial dual coil (implantable)
C1896	Lead, cardioverter-defibrillator, other than endocardial single or dual coil (implantable)
C1899	Lead, pacemaker/cardioverter-defibrillator combination (implantable)

Substernal Implantable Defibrillators

0571T	Insertion or replacement of implantable cardioverter-defibrillator system with substernal electrode(s), including all imaging guidance and electrophysiological evaluation (includes defibrillation threshold evaluation, 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

General Information

Guideline Scope

This guideline addresses the appropriate clinical indications for transvenous and subcutaneous implantable cardioverter defibrillators (ICDs) for management of ventricular arrhythmia. Use of external defibrillators and cardiac resynchronization devices is not addressed in this document.

Definitions

Guideline-directed medical therapy (GDMT): Maximum tolerated doses of appropriately titrated medication (to include beta blockers, ACE inhibitors or ARBs, aldosterone antagonists and diuretics in patients with left ventricular dysfunction). When a particular medication class is contraindicated, GDMT definition can exclude that class.

Sustained ventricular tachycardia: Ventricular tachycardia that persists for at least 30 seconds or requiring termination due to hemodynamic instability.

Structural heart disease: Left ventricular dysfunction (LVEF < 50%), prior myocardial infarction, moderate or severe valvular heart disease or complex congenital heart disease.

New York Heart Association (NYHA) functional class: Symptom-based classification of the severity of heart failure as outlined below.

- Class I. Individuals with cardiac disease but without resulting limitation of physical activity; ordinary physical activity does not cause undue fatigue, palpitation, dyspnea, or anginal pain; symptoms only occur on severe exertion.
- Class II. Individuals with cardiac disease resulting in slight limitation of physical activity; they are comfortable at rest; ordinary physical activity, (e.g., moderate physical exertion, such as carrying shopping bags up several flights of stairs) results in fatigue, palpitation, dyspnea, or anginal pain.
- Class III. Individuals with cardiac disease resulting in marked limitation of physical activity; they are comfortable at rest; less than ordinary activity causes fatigue, palpitation, dyspnea or anginal pain;
- Class IV. Individuals with cardiac disease resulting in inability to carry on any physical activity without discomfort; symptoms of heart failure or the anginal syndrome may be present even at rest; if any physical activity is undertaken, discomfort is increased.

Clinical Indications

Transvenous Implantable Cardioverter Defibrillators

Transvenous ICD placement is considered medically necessary in ANY of the following scenarios when survival with good functional status for more than one year is anticipated:

- Following cardiac arrest due to ventricular fibrillation or tachycardia when no completely reversible cause can be identified
- Spontaneous sustained ventricular tachycardia in an individual with structural heart disease
- Syncope which is otherwise unexplained in an individual with structural heart disease
- Syncope which is otherwise unexplained in an individual with ischemic heart disease and inducible sustained monomorphic ventricular tachycardia on electrophysiology (EP) study
- Nonischemic dilated cardiomyopathy in an individual ≤ 70 years of age, when, following 90 days of GDMT, **BOTH** of the following are still present:
    - Left ventricular ejection fraction (LVEF) ≤ 35%
    - NYHA functional class II or III
- Ischemic cardiomyopathy when **ANY** of the following apply:
    - LVEF is ≤ 30% due to myocardial infarction ≥ 40 days previously in an individual with NYHA functional class I despite GDMT, who is at least 90 days post revascularization (if revascularization has been performed)
    - LVEF is ≤ 35% due to myocardial infarction ≥ 40 days previously in an individual with NYHA functional class II or III despite GDMT, who is at least 90 days post revascularization (if revascularization has been performed)
    - LVEF is ≤ 40% due to prior myocardial infarction in an individual who has spontaneous nonsustained ventricular tachycardia AND positive electrophysiology study performed ≥ 96 hours following myocardial infarction
- Congenital heart disease when **ANY** of the following apply:
    - History of cardiac arrest thought to be (or known to be) due to ventricular arrhythmia
    - Ventricular tachycardia with hemodynamic instability not amenable to other treatment options (e.g., surgical repair, ablation) and following institution of GDMT for ventricular dysfunction (if present)
    - Unexplained syncope in an individual with repaired congenital heart disease who has moderate LV dysfunction (LVEF < 40%) or marked left ventricular hypertrophy
- Established diagnosis of hypertrophic cardiomyopathy when **ANY** of the following apply:
    - History of cardiac arrest thought to be (or known to be) due to ventricular arrhythmia in the absence of reversible cause
    - Syncope or hemodynamic compromise known to be related to ventricular tachycardia
    - Maximum LV wall thickness ≥ 30 mm
    - Sudden cardiac death presumed related to hypertrophic cardiomyopathy in a first-degree relative
    - Unexplained syncope within the preceding 6 months

- Abnormal blood pressure response to exercise or spontaneous nonsustained ventricular tachycardia in an individual who has **ANY** of the following:
    - Age < 30 years
    - Delayed hyperenhancement on cardiac MRI
    - Left ventricular outflow tract obstruction
    - Syncope within the preceding 5 years
    - Left ventricular aneurysm
    - Left ventricular ejection fraction < 50%
- Established diagnosis of arrhythmogenic right ventricular dysplasia when **ANY** of the following apply:
    - History of cardiac arrest
    - Sustained ventricular tachycardia
    - Left and/or right ventricular ejection fraction ≤ 35% in an individual who is on GDMT
    - Syncope thought to be (or known to be) due to ventricular arrhythmia
- Established diagnosis of long QT syndrome in an individual with syncope or ventricular tachycardia despite beta blocker therapy (or in whom beta blockers are contraindicated)
- Established diagnosis of short QT syndrome in an individual who has a history of cardiac arrest or sustained ventricular tachycardia or fibrillation
- Established diagnosis of Brugada syndrome in an individual with spontaneous type 1 electrocardiographic pattern when **ANY** of the following apply:
    - History of cardiac arrest
    - Sustained ventricular tachycardia or ventricular fibrillation
    - History of syncope thought to be (or known to be) due to ventricular arrhythmia
- Catecholaminergic polymorphic ventricular tachycardia in an individual with recurrent sustained ventricular tachycardia or recurrent syncope despite beta blocker therapy (or in whom beta blockers are contraindicated)
- Established diagnosis of cardiac sarcoidosis when **ANY** of the following apply:
    - History of cardiac arrest
    - LVEF ≤ 35% in an individual who is on GDMT
    - Spontaneous or induced sustained ventricular tachycardia
    - Indication for permanent pacemaker
    - LVEF > 35% with history of syncope or evidence of extensive myocardial scar by cardiac MRI or PET scan
- An outpatient who has met criteria for, and is awaiting, heart transplant or ventricular assist device and who is NYHA functional class IV
- Device replacement when **EITHER** of the following apply:
    - Generator end-of-life criteria are present
    - The generator pocket needs to be opened for another reason (e.g., lead revision) **AND** the device is within 3 years of reaching end-of-life criteria

Subcutaneous Implantable Cardioverter Defibrillators

Subcutaneous ICD placement is considered medically necessary when ALL of the following criteria are met:

- **ONE** of the above criteria for transvenous ICD placement is present
- The individual does not require pacing for bradycardia, overdrive pacing for termination of ventricular tachycardia, or cardiac resynchronization
- The individual does not have incessant ventricular tachycardia
- At least **ONE** of the following applies:
    - Inability to secure venous access
    - Immunocompromised individual
    - Individual with recurrent transvenous lead-related, device-pocket, or systemic infections
    - Individual with endocarditis
    - Individual is ≤ 21 years of age

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History

Status	Review Date	Effective Date	Action
Revised	07/18/2023 and 09/07/2023	03/17/2024	Independent Multispecialty Physician Panel (IMPP) review. Transvenous ICD criteria expanded to allow replacement when the pocket is opened for another reason when device is near end of life; added age limit for individuals with non-ischemic dilated cardiomyopathy. Subcutaneous ICD placement criteria expanded for individuals ≤ 21 years of age. Updated references. Removed inpatient CPT codes 33202, 33203, and 33243. Added required language to General Clinical Guideline per new Medicare regulations.
Updated	n/a	09/10/2023	Added HCPCS C1899.
Revised	05/26/2021	11/07/2021	IMPP review. Added indication for device replacement when generator end-of-life criteria are present.
Updated	08/26/2020	01/01/2021	Original effective date. Updated code set.
Reviewed	12/12/2019	-	Literature review. Added CPT code 0571T.
Reviewed	11/28/2018	-	IMPP review.