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Clinical Appropriateness Guidelines

Cardiovascular

Appropriate Use Criteria: Cardiac Resynchronization Therapy

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.

Cardiac Resynchronization Therapy

General Information

Description and Scope

Disparity in the timing of regional ventricular contraction, mechanical dyssynchrony, is seen in some patients with congestive heart failure and has adverse prognostic implications. Over the past 2 decades it has been established that biventricular pacing is associated with improved outcomes and/or well-being in some patients with mechanical dyssynchrony. This treatment is known as cardiac resynchronization therapy (CRT). This guideline addresses the appropriate use of CRT.

Pacing of the left ventricle for CRT is achieved either via the coronary sinus (in which case the pacing lead is epicardial) or by implanting a wireless pacemaker on the endocardial surface of endocardium. Endocardial wireless pacemakers are triggered by ultrasound emitted from a transmitter which is triggered by the right ventricular pacing device. Both traditional transvenous and wireless CRT are addressed in this guideline. Evidence supporting the use of wireless left ventricular pacing is evolving. Thus far, published studies have been limited by small sample size, lack of a randomized control group, restriction to highly specialized centers, and short follow-up duration. Furthermore, wireless CRT is not FDA approved at this time.

Before consideration is given to CRT, reversible causes of heart failure should be excluded or corrected (e.g., ischemia, tachycardia-mediated cardiomyopathy, or alcohol), and the patient should be reassessed following an adequate trial of guideline-directed pharmacological therapy.

Cardiac resynchronization therapy devices, whether used to prolong survival or improve well-being, should be reserved for patients whose general health is such that survival with meaningful quality of life (with the device) is expected to exceed one year.

This guideline outlines the clinical scenarios in which CRT is considered appropriate. Although many patients for whom CRT is deemed appropriate will also meet criteria for an implantable cardioverter defibrillator (ICD), patients who meet criteria for both CRT and ICD are managed with a single device capable of performing both functions. Such devices are known as CRT-implantable cardioverter-defibrillator (CRT-D) devices to differentiate them from CRT-pacemaker (CRT-P) devices, which perform pacing function and are not capable of providing defibrillation.

Definitions

Guideline-directed medical therapy: Maximum tolerated doses of appropriately titrated heart failure medication (to include beta blockers, ACE inhibitors or ARBs, aldosterone antagonists and diuretics). When a particular medication class is contraindicated, guideline-directed medical therapy definition can exclude that class.

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

CRT-P device implantation

CRT-P is considered medically necessary when, following an adequate trial* of guideline-directed medical therapy for congestive heart failure, ALL of the following are present:

- Sinus rhythm
- Left ventricular ejection fraction (LVEF) ≤ 35%
- Prolonged QRS duration with **EITHER** of the following:
  - ≥ 150 milliseconds (any morphology)
  - 130-149 milliseconds with LBBB morphology
- NYHA class II, class III, or ambulatory class IV heart failure symptoms
- Correctable causes of congestive heart failure (e.g., ischemia, tachycardia-mediated cardiomyopathy) have been appropriately addressed

In this context, an **adequate trial of guideline-directed medical therapy means either 3 months of therapy following diagnosis or 40 days of therapy following the most recent myocardial infarction.*

***Note**: Some patients who meet all criteria above may also meet criteria for an implantable defibrillator. In such situations, at the discretion of the provider (and following discussion with the patient), either CRT-D or CRT-P is considered appropriate.*

CRT-P is considered medically necessary when, following an adequate trial* of guideline-directed medical therapy for congestive heart failure, ALL of the following are present:

- Atrial fibrillation
- Left ventricular ejection fraction (LVEF) ≤ 35%
- QRS duration ≥ 130 milliseconds *(**Note**: Patients who undergo AV node ablation and have a post-ablation paced QRS duration of ≥ 130 milliseconds can be considered to have met this criterion*)
- NYHA class III or ambulatory class IV
- Strategy to ensure high rate (≥ 90%) biventricular capture (adequate rate control medications or planning AV node ablation) or expectation that sinus rhythm will be restored
- Correctable causes of congestive heart failure (e.g., ischemia, tachycardia-mediated cardiomyopathy) have been appropriately addressed

In this context, an **adequate trial of guideline-directed medical therapy means either 3 months of therapy following diagnosis or 40 days of therapy following the most recent myocardial infarction.*

***Note**: Some patients who meet all criteria above may also meet criteria for an implantable defibrillator. In such situations, at the discretion of the provider (and following discussion with the patient), either CRT-D or CRT-P is considered appropriate.*

CRT-P is considered medically necessary for patients who meet ALL of the following:

- Sinus rhythm or atrial fibrillation
- Criteria for permanent pacemaker implantation
- Left ventricular ejection fraction (LVEF) < 50%

- NYHA class I-III
- Is expected to have high degree of ventricular pacing (close to 100%)
- Correctable causes of congestive heart failure (e.g., ischemia, tachycardia-mediated cardiomyopathy) have been appropriately addressed

CRT-P or CRT-D replacement is considered medically necessary 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

Exclusions

Wireless CRT

Wireless CRT is considered **not medically necessary** in all scenarios.

Rationale

Much of the relevant data regarding the clinical utility of CRT are from several clinical trials published between 2002 and 2010, including MIRACLE, COMPANION, CARE-HF, REVERSE, MADIT-CRT, and RAFT. Among patients with heart failure, these studies have shown reductions in death and hospitalization for heart failure with CRT. Guideline criteria are based on the inclusion criteria for these studies and are in concordance with professional society guidelines.[13]

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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

00530	Anesthesia for permanent transvenous pacemaker insertion
00534	Anesthesia for transvenous insertion or replacement of pacing cardioverter/defibrillator
33208	Insertion of new or replacement of permanent pacemaker with transvenous electrode(s); atrial and ventricular
33214	Upgrade of implanted pacemaker system, conversion of single chamber system to dual chamber system (includes removal of previously placed pulse generator, testing of existing lead, insertion of new lead, insertion of new pulse generator)
33221	Insertion of pacemaker pulse generator only; with existing multiple leads
33224	Insertion of pacing electrode, cardiac venous system, for left ventricular pacing; with attachment to previously placed pacemaker or implantable defibrillator pulse generator (including revision of pocket, removal, insertion, and/or replacement of existing generator)
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)
33226	Repositioning of previously implanted cardiac venous system (left ventricular) electrode (including removal, insertion and/or replacement of existing generator)
33229	Removal of permanent pacemaker pulse generator with replacement of pacemaker pulse generator; multiple lead system
33241	Removal of implantable defibrillator pulse generator only
33244	Removal of single or dual chamber pacing cardioverter-defibrillator electrode(s); by transvenous extraction
33249	Insertion or replacement of permanent implantable defibrillator system, with transvenous lead(s), single or dual chamber
33263	Removal of implantable defibrillator pulse generator with replacement of implantable defibrillator pulse generator; dual lead system
33264	Removal of implantable defibrillator pulse generator with replacement of implantable defibrillator pulse generator; multiple lead system
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
0515T	Insertion of wireless cardiac stimulator for left ventricular pacing, including device interrogation and programming, and imaging supervision and interpretation, when performed; complete system (includes electrode and generator [transmitter and battery])
0516T	Insertion of wireless cardiac stimulator for left ventricular pacing, including device interrogation and programming, and imaging supervision and interpretation, when performed; electrode only

0517T	Insertion of wireless cardiac stimulator for left ventricular pacing, including device interrogation and programming, and imaging supervision and interpretation, when performed; pulse generator component(s) (battery and/or transmitter) only
0518T	Removal of only pulse generator component(s) (battery and/or transmitter) of wireless cardiac stimulator for left ventricular pacing
0519T	Removal and replacement of wireless cardiac stimulator for left ventricular pacing; pulse generator component(s) (battery and/or transmitter)
0520T	Removal and replacement of wireless cardiac stimulator for left ventricular pacing; pulse generator component(s) (battery and/or transmitter), including placement of a new electrode
0521T	Interrogation device evaluation (in person) with analysis, review and report, includes connection, recording, and disconnection per patient encounter, wireless cardiac stimulator for left ventricular pacing
0522T	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, including review and report, wireless cardiac stimulator for left ventricular pacing
0861T	Removal of pulse generator for wireless cardiac stimulator for left ventricular pacing; both components (battery and transmitter)
0862T	Relocation of pulse generator for wireless cardiac stimulator for left ventricular pacing, including device interrogation and programming; battery component only
0863T	Relocation of pulse generator for wireless cardiac stimulator for left ventricular pacing, including device interrogation and programming; transmitter component only
C7537	Insertion of new or replacement of permanent pacemaker with atrial transvenous electrode(s), with 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)
C7538	Insertion of new or replacement of permanent pacemaker with ventricular transvenous electrode(s), with 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)
C7539	Insertion of new or replacement of permanent pacemaker with atrial and ventricular transvenous electrode(s), with 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)
C7540	Removal of permanent pacemaker pulse generator with replacement of pacemaker pulse generator, dual lead system, with 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)
G0448	Insertion or replacement of a permanent pacing cardioverter-defibrillator system with transvenous lead(s), single or dual chamber with insertion of pacing electrode, cardiac venous system, for left ventricular pacing

History

Status	Review Date	Effective Date	Action
Revised	01/23/2024	10/20/2024	Independent Multispecialty Physician Panel (IMPP) review. Added exclusion for Wireless CRT. Added references. Added CPT codes 0515T, 0516T, 0517T, 0518T, 0519T, 0520T, 0521T, 0522T, 0861T, 0862T, 0863T.
Revised	07/18/2023	03/17/2024	IMPP review. Added CRT-D replacement appropriate when generator pocket opened for another reason near end of life of device (aligns with ICD guidelines). Added HCPCS code C7537, C7538, C7539, C7540; removed inpatient CPT 33243.
Updated	01/23/2024	Unchanged	IMPP review. Expanded guideline rationale. Updated references. Added required language to General Clinical Guideline per new Medicare regulations.
Revised	05/09/2022	04/09/2023	IMPP review. Rephrased criteria around prolonged QRS duration for clarity. Updated references. Added CPT code 33221. Removed HCPCS code C1824.

Status	Review Date	Effective Date	Action
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.
Revised	05/14/2020	-	Replaced “optimal” with “guideline directed” and moved note in CRT-P.
Reviewed	05/11/2019	-	IMPP review.