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

Clinical Appropriateness Guidelines

Cardiology

Appropriate Use Criteria: Cardiac Resynchronization Therapy

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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. As used by Carelon, the Guidelines establish objective and evidence-based criteria for medical necessity determinations where possible. In the process, multiple functions are accomplished:

- To establish criteria for when services are medically necessary (i.e., in general, shown to be effective in improving health outcomes and considered the most appropriate level of service)
- 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 advocate for 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 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. Relevant citations are included in the References section attached to each Guideline. Carelon reviews all of its Guidelines at least annually.

Carelon makes its Guidelines publicly available on its website twenty-four hours a day, seven days a week. Copies of the Carelon Clinical Appropriateness Guidelines are also available upon oral or written request. 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. 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 should outweigh any potential harms that may result (net benefit).
- Current literature and/or standards of medical practice should support that the recommended intervention offers the greatest net benefit among competing alternatives.
- Based on the clinical evaluation, current literature, and standards of medical practice, there exists a reasonable likelihood that the intervention will change management and/or lead to an improved outcome for the patient.

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 supersede the requirements set forth above. During the peer-to-peer conversation, factors such as patient acuity and setting of service may also be taken into account.

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.

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.

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 appropriate 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%
- QRS duration ≥ 150 milliseconds or LBBB with QRS duration 130-149 milliseconds
- 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

***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 appropriate 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

***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 appropriate 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

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.*

CRT-P or CRT-D is considered appropriate for patients whose current device has reached generator end-of-life criteria.

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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)
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
33243	Removal of single or dual chamber pacing cardioverter-defibrillator electrode(s); by thoracotomy
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
C1824	Generator, cardiac contractility modulation (implantable)
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	05/26/2021	11/07/2021	Independent Multispecialty Physician Panel (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.