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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

Cardiovascular

Appropriate Use Criteria: Permanent Implantable Pacemakers

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.

Permanent Implantable Pacemakers

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
33206	Insertion of new or replacement of permanent pacemaker with transvenous electrode(s); atrial
33207	Insertion of new or replacement of permanent pacemaker with transvenous electrode(s); ventricular
33208	Insertion of new or replacement of permanent pacemaker with transvenous electrode(s); atrial and ventricular
33212	Insertion of pacemaker pulse generator only; single existing single lead
33213	Insertion of pacemaker pulse generator only; with existing dual leads
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)
33215	Repositioning of previously implanted transvenous pacemaker or ICD (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 ICD
33220	Repair of 2 transvenous electrodes for permanent pacemaker or ICD
33222	Relocation of skin pocket for pacemaker
33227	Removal of permanent pacemaker pulse generator with replacement of pacemaker pulse generator; single lead system
33228	Removal of permanent pacemaker pulse generator with replacement of pacemaker pulse generator; dual lead system
33233	Removal of permanent pacemaker pulse generator only
33234	Removal of transvenous pacemaker electrode(s); single lead system, atrial or ventricular
33235	Removal of transvenous pacemaker electrode(s); dual lead system
33274	Transcatheter insertion or replacement of permanent leadless pacemaker, right ventricular, including imaging guidance (e.g., fluoroscopy, venous ultrasound, ventriculography, femoral venography) and device evaluation (e.g., interrogation or programming), when performed
33275	Transcatheter removal of permanent leadless pacemaker, right ventricular, including imaging guidance (eg, fluoroscopy, venous ultrasound, ventriculography, femoral venography), when performed
C1785	Pacemaker, dual-chamber, rate-responsive (implantable)
C1786	Pacemaker, single-chamber, rate-responsive (implantable)
C2619	Pacemaker, dual-chamber, non-rate-responsive (implantable)
C2620	Pacemaker, single-chamber, non-rate-responsive (implantable)
C2621	Pacemaker, other than single or dual chamber (implantable)

Dual-chamber leadless pacemakers

0795T	Transcatheter insertion of permanent dual-chamber leadless pacemaker, including imaging guidance (eg, fluoroscopy, venous ultrasound, right atrial angiography, right ventriculography, femoral venography) and device

	evaluation (eg, interrogation or programming), when performed; complete system (ie, right atrial and right ventricular pacemaker components)
0796T	Transcatheter insertion of permanent dual-chamber leadless pacemaker, including imaging guidance (eg, fluoroscopy, venous ultrasound, right atrial angiography, right ventriculography, femoral venography) and device evaluation (eg, interrogation or programming), when performed; right atrial pacemaker component (when an existing right ventricular single leadless pacemaker exists to create a dual-chamber leadless pacemaker system)
0797T	Transcatheter insertion of permanent dual-chamber leadless pacemaker, including imaging guidance (eg, fluoroscopy, venous ultrasound, right atrial angiography, right ventriculography, femoral venography) and device evaluation (eg, interrogation or programming), when performed; right ventricular pacemaker component (when part of a dual-chamber leadless pacemaker system)
0798T	Transcatheter removal of permanent dual-chamber leadless pacemaker, including imaging guidance (eg, fluoroscopy, venous ultrasound, right atrial angiography, right ventriculography, femoral venography), when performed; complete system (ie, right atrial and right ventricular pacemaker components)
0799T	Transcatheter removal of permanent dual-chamber leadless pacemaker, including imaging guidance (eg, fluoroscopy, venous ultrasound, right atrial angiography, right ventriculography, femoral venography), when performed; right atrial pacemaker component
0800T	Transcatheter removal of permanent dual-chamber leadless pacemaker, including imaging guidance (eg, fluoroscopy, venous ultrasound, right atrial angiography, right ventriculography, femoral venography), when performed; right ventricular pacemaker component (when part of a dual-chamber leadless pacemaker system)
0801T	Transcatheter removal and replacement of permanent dual-chamber leadless pacemaker, including imaging guidance (eg, fluoroscopy, venous ultrasound, right atrial angiography, right ventriculography, femoral venography) and device evaluation (eg, interrogation or programming), when performed; dual-chamber system (ie, right atrial and right ventricular pacemaker components)
0802T	Transcatheter removal and replacement of permanent dual-chamber leadless pacemaker, including imaging guidance (eg, fluoroscopy, venous ultrasound, right atrial angiography, right ventriculography, femoral venography) and device evaluation (eg, interrogation or programming), when performed; right atrial pacemaker component
0803T	Transcatheter removal and replacement of permanent dual-chamber leadless pacemaker, including imaging guidance (eg, fluoroscopy, venous ultrasound, right atrial angiography, right ventriculography, femoral venography) and device evaluation (eg, interrogation or programming), when performed; right ventricular pacemaker component (when part of a dual-chamber leadless pacemaker system)
0804T	Programming device evaluation (in person) with iterative adjustment of implantable device to test the function of device and to select optimal permanent programmed values, with analysis, review, and report, by a physician or other qualified health care professional, leadless pacemaker system in dual cardiac chambers

General Information

Guideline Scope

This guideline addresses the appropriate use of permanent implantable pacemakers for the management of bradyarrhythmias. It does not address the use of temporary pacemakers, pacemakers for management of heart failure (cardiac resynchronizations therapy), or implantable defibrillators. Occasionally, the clinical scenario requiring implantation of a permanent pacemaker arises during hospitalization for another reason (e.g., following valve replacement, bypass surgery, or myocardial infarction). These procedures do not require prior authorization and are therefore not addressed in this document.

Overriding Considerations

- An arrhythmia is considered to be “documented” when it has been permanently recorded such that a copy can be provided on request.
- An arrhythmia is considered to be “symptomatic” when symptoms have occurred at the same time as the arrhythmia. When symptoms and the arrhythmia are temporally separated, the arrhythmia cannot be described as symptomatic.

- In general, placement of a pacemaker is not appropriate in patients who are currently taking medications which cause bradyarrhythmias and/or conduction disturbance. Whenever possible, such medications should be discontinued unless there are no acceptable alternative therapies.
- The decision to treat bradyarrhythmias or conduction disturbance with a permanent pacemaker assumes that reversible causes (e.g., electrolyte disturbance, hypothermia, drug toxicity, hypothyroidism, infection, inflammation, ischemia, etc.) have been excluded.
- Pacemaker device selection and utilization (manufacturer/capabilities/mode settings, etc.) are outside the scope of this guideline, are at the discretion of the physician, and should be optimized to the patient's individual clinical situation.
- When a patient meets criteria for permanent pacemaker therapy and has an indication for cardiac resynchronization therapy or implantable defibrillator, a single device which meets all of the patient's clinical needs should be selected.

Definitions

Extracted from 2018 ACC/AHA/HRS guideline on the evaluation and management of patients with bradycardia and cardiac conduction delay.[13]

Symptomatic arrhythmia: For purposes of guideline interpretation, symptomatic arrhythmia refers to a documented arrhythmia that is directly responsible for development of the clinical manifestations of syncope or presyncope, transient dizziness or lightheadedness, heart failure symptoms, or confusional states resulting from cerebral hypoperfusion attributable to slow heart rate. For an arrhythmia to be considered symptomatic, a temporal association between the arrhythmia and symptoms must be demonstrated.

Sinus node dysfunction refers to dysfunction of the sinus node or surrounding atrial tissue which may give rise to any of the following rhythm disturbances:

- Sinus bradycardia (sinus rate < 50 bpm)
- Ectopic atrial bradycardia (atrial depolarization attributable to an atrial pacemaker other than the sinus node with a rate < 50 bpm)
- Sinoatrial exit block: Evidence that blocked conduction between the sinus node and adjacent atrial tissue is present. (Multiple electrocardiographic manifestations including "group beating" of atrial depolarization and sinus pauses).
- Sinus pause: Sinus node depolarizes > 3 seconds after the last atrial depolarization
- Sinus node arrest: No evidence of sinus node depolarization
- Tachycardia-bradycardia ("tachy-brady") syndrome: Sinus bradycardia, ectopic atrial bradycardia, or sinus pause alternating with periods of abnormal atrial tachycardia, atrial flutter, or atrial fibrillation. The tachycardia may be associated with suppression of sinus node automaticity and a sinus pause of variable duration when the tachycardia terminates.
- Chronotropic incompetence: Broadly defined as the inability of the heart to increase its rate commensurate with increased activity or demand, in many studies translates to failure to attain 80% of expected heart rate reserve during exercise.
- Isorhythmic dissociation: Atrial depolarization (from either the sinus node or ectopic atrial site) is slower than ventricular depolarization (from an atrioventricular nodal, His bundle, or ventricular site).

Atrioventricular block is the slowing or absence of impulse conduction at the atrioventricular (AV) node. It may manifest as any of the following:

- First-degree atrioventricular block: P waves associated with 1:1 atrioventricular conduction and a PR interval > 200 milliseconds
- Second-degree atrioventricular block: P waves with a constant rate (< 100 bpm) where atrioventricular conduction is present but not 1:1

    - Mobitz type I: P waves with a constant rate (< 100 bpm) with a periodic single nonconducted P wave associated with P waves before and after the nonconducted P wave with inconstant PR intervals
    - Mobitz type II: P waves with a constant rate (< 100 bpm) with a periodic single nonconducted P wave associated with other P waves before and after the nonconducted P wave with constant PR intervals (excluding 2:1 atrioventricular block)
    - 2:1 atrioventricular block: P waves with a constant rate (or near constant rate because of ventriculophasic sinus arrhythmia) rate (< 100 bpm) where every other P wave conducts to the ventricles
    - Advanced, high-grade or high-degree atrioventricular block: ≥ 2 consecutive P waves at a constant physiologic rate that do not conduct to the ventricles with evidence for some atrioventricular conduction
- Third-degree atrioventricular block (complete heart block): No evidence of atrioventricular conduction

Infranodal block: Atrioventricular conduction block where clinical evidence or electrophysiologic evidence suggests that the conduction block occurs distal to the atrioventricular node

Vagally mediated atrioventricular block: Any type of atrioventricular block mediated by heightened parasympathetic tone

Complex ventricular ectopy: Multifocal ectopy, sustained or non-sustained ventricular tachycardia, bigeminy, couplets, triplets or R-on-T premature ventricular complexes

Neuromuscular diseases: Conduction system dysfunction is a feature of some neuromuscular diseases. For purposes of guideline interpretation, patients can be considered to have a neuromuscular disease if they have any of the following: myotonic dystrophy (type 1), Emery-Dreifuss muscular dystrophy, limb girdle (type 1b) muscular dystrophy, dystrophinopathies (Duchenne or Becker muscular dystrophy), or Kearns-Sayre syndrome.

Clinical Indications

Documented sinus node dysfunction

Permanent pacemaker placement is considered medically necessary for documented sinus node dysfunction when the patient takes no medications which would cause sinus node dysfunction (or withholding/dose reduction of such medications would be contraindicated) and **ANY** of the following apply:

- Symptomatic arrhythmias with sinus node dysfunction when symptoms are clearly attributable to the arrhythmia
- Symptomatic chronotropic incompetence
- Symptomatic tachy-brady syndrome when the symptoms are clearly attributable to bradyarrhythmia

***Note**: In the absence of symptoms which can be temporally correlated with sinus node dysfunction, there is no minimum heart rate or pause duration at which permanent pacemaker placement would be considered appropriate.*

Documented atrioventricular (AV) block

Permanent pacemaker placement is considered medically necessary for documented AV block when reversible causes of AV block are absent, the patient takes no medications which would cause AV node dysfunction (or withholding such medications would be contraindicated), and **ANY** of the following apply:

- Acquired third-degree AV block (symptomatic or asymptomatic)
- Acquired high grade second-degree block (symptomatic or asymptomatic)
- Acquired Mobitz type II second-degree AV block (symptomatic or asymptomatic)

- Symptomatic Mobitz type I second-degree AV block when symptoms are clearly attributable to the AV block
- Symptomatic first-degree AV block when PR interval is ≥ 300 milliseconds and symptoms are clearly attributable to the AV block
- Permanent atrial fibrillation and symptomatic bradycardia
- Neuromuscular disease with expected survival more than one year and **ANY** of the following:
    - Third-degree AV block
    - Second-degree AV block (type 1, type 2, 2:1 AV block, and high-grade AV block)
    - PR interval > 240 milliseconds
    - HV interval ≥ 70 milliseconds
- Infiltrative cardiomyopathy (e.g., sarcoidosis, amyloidosis) with expected survival more than one year and **ANY** of the following:
    - Third-degree AV block
    - Second-degree (Mobitz type II)
    - High-grade AV block
- Congenital heart disease with **ANY** of the following:
    - Symptomatic bradycardia related to AV block
    - Congenital complete AV block with **ANY** of the following:
        - Bradycardia (symptomatic or asymptomatic)
        - Escape rhythm with a wide QRS complex
        - Mean daytime heart rate < 50 beats per minute
        - Complex ventricular ectopy
        - Ventricular dysfunction
- Postoperative AV block that is not expected to resolve with **ANY** of the following:
    - Third-degree AV block
    - Second-degree (Mobitz type II)
    - High-grade AV block

Bundle branch block or fascicular block

Permanent pacemaker placement is considered medically necessary for bundle branch block or fascicular block (with 1:1 atrioventricular conduction) when **ANY** of the following apply:

- Alternating bundle branch block
- Syncope of unknown cause in a patient who has bundle branch block and **EITHER** of the following:
    - HV interval ≥ 70 milliseconds
    - Evidence of infranodal block on electrophysiology study
- Neuromuscular disease with expected survival more than one year and **ANY** of the following:
    - HV interval ≥ 70 milliseconds
    - QRS duration > 120 milliseconds
    - Fascicular block

- Anderson-Fabry disease with expected survival more than one year and QRS duration > 110 milliseconds

Leadless pacemakers

A single chamber leadless pacemaker is considered **medically necessary** when **BOTH** of the following conditions apply:

- The individual has an indication for a pacemaker
- A leaded transvenous pacemaker cannot be placed because of **ONE** of the following:
    - Venous access issues
    - History of or high risk for cardiac implanted electronic device (CIED) infection
    - Prosthetic tricuspid valve

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History

Status	Review Date	Effective Date	Action
Revised	07/18/2023	03/17/2024	Independent Multispecialty Physician Panel (IMPP) review. Added new criteria for single chamber leadless pacemakers. Added CPT codes 00530, 33275, 0795T, 0796T, 0797T, 0798T, 0799T, 0800T, 0801T, 0802T, 0803T, 0804T. Added required language to General Clinical Guideline per new Medicare regulations.
Updated	-	10/01/2023	Added CPT codes 33215, 33216, 33217, 33218, 33220, 33222, 33233, 33234, 33235. Added HCPCS codes C1785, C1786, C2619, C2620, C2621.
Created/ Reaffirmed	08/29/2022	01/01/2023	IMPP review. Added references. Guidelines reaffirmed. Original effective date.
Reviewed	02/03/2020	01/01/2023	IMPP review.