

## Evolent Clinical Guideline **3227315** for Pacemaker Insertion

<b>Guideline Number:</b>	<b>Applicable Codes</b>			
Evolent_CG_7315				
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# STATEMENT

## General Information

- *It is an expectation that all patients receive care/services from a licensed clinician. All appropriate supporting documentation, including recent pertinent office visit notes, laboratory data, and results of any special testing must be provided. If applicable: All prior relevant imaging results and the reason that alternative imaging cannot be performed must be included in the documentation submitted.*
- *Where a specific clinical indication is not directly addressed in this guideline, medical necessity determination will be made based on widely accepted standard of care criteria. These criteria are supported by evidence-based or peer-reviewed sources such as medical literature, societal guidelines and state/national recommendations.*
- *The guideline criteria in the following sections were developed utilizing evidence-based and peer-reviewed resources from medical publications and societal organization guidelines as well as from widely accepted standard of care, best practice recommendations.*

## Purpose

This guideline is not intended to specify the type of bradycardia pacing device. CRT (cardiac resynchronization therapy or biventricular pacing) and ICD (implantable cardioverter defibrillator) implantation are covered in separate guidelines. Pacemaker implantation generally serves to address bradycardia, with the intention of ameliorating related symptoms, preventing complications of syncope, and/or reducing mortality risk.

## Clinical Reasoning

All criteria are substantiated by the latest evidence-based medical literature. To enhance transparency and reference, Appropriate Use (AUC) scores, when available, are diligently listed alongside the criteria.

This guideline first defaults to AUC scores established by published, evidence-based guidance endorsed by professional medical organizations. In the absence of those scores, we adhere to a standardized practice of assigning an AUC score of 6. This score is determined by considering variables that ensure the delivery of patient-centered care in line with current guidelines, with a focus on achieving benefits that outweigh associated risks. This approach aims to maintain a robust foundation for decision-making and underscores our commitment to upholding the highest standards of care.<sup>(1-5)</sup>

# INDICATIONS FOR PACEMAKERS IN ADULTS

Excludes conditions that are expected to resolve.

## **Sinus Node Dysfunction (SND)** (6-9)

- Documented symptomatic sinus bradycardia, including frequent sinus pauses (6,7)
- Symptomatic chronotropic incompetence (broadly defined as an inability to increase heart rate commensurate with activity or demand), documented by stress test or cardiac monitoring data (Holter/MCOT/Electrocardiography (ECG)) recording data (6,7)
- Symptomatic sinus bradycardia that resultsresulting from required guideline-directed medical therapy (GDMT) for which there is no alternative treatment (6,7)
- Heart rate less than< 40 beats per minute (bpm) while awake, even without definite association with significant symptoms consistent with bradycardia (6)
- Tachycardia-bradycardia syndrome and symptoms attributable to bradycardia (7,8)
- Syncope of unexplained origin with clinically significant SND, either documented or provoked in electrophysiologic study (EPS) (6)
- With LBBB and LVEF < 50% (AUC SCORE 6)

## **Acquired Atrioventricular (AV) Block** (6,7,9)

### **First-Degree AV Block**

- Marked first-degree Mobitz Type 1 AV block with symptoms clearly attributable to the AV block (7)
- First-degree block with a long PR interval (>200 ms) and LVEF ≤ 35% (AUC SCORE 7) or 36-50% (AUC SCORE 6)
- First-degree AV block with “pacemaker syndrome” symptoms (chronic fatigue, dyspnea on exertion, symptomatic hypotension) or hemodynamic compromise (7)

### **Second Degree AV Block (Mobitz Types I and II)**

- Second degree Mobitz Type 1 AV Block with a narrow QRS and LVEF ≤ 35% (AUC SCORE 7) or 36-50% (AUC SCORE 6)
- Marked second-degree Mobitz Type 1 AV block with symptoms clearly attributable to the AV block (6,7)
- Second-degree AV block with “pacemaker syndrome” symptoms (chronic fatigue, dyspnea on exertion, symptomatic hypotension) or hemodynamic compromise (6)
- Second-degree Mobitz Type II AV block regardless of symptoms (6,7)
- Advanced second-degree AV block (6)

- Second-degree AV block associated with a wide QRS, or EPS-documented intra- or infra-His conduction delay of 70 ms or greater<sup>(6)</sup>
- Symptomatic bradycardia associated with second-degree AV block, either Mobitz I or II<sup>(6)</sup>

### ***Third-Degree/Complete AV Block***

- Third-degree (complete) AV block, intermittent with LVEF ≤ 35% (AUC SCORE 7) or 36-50% (AUC SCORE 6) or persistent, regardless of symptoms and LVEF < 50% (AUC SCORE 7) or > 50% (AUC SCORE 6)
  - If the only symptom is a narrow junctional escape rhythm and LVEF is > 50%, pacemaker is not indicated (AUC SCORE 5)
- High-grade AV block, regardless of symptoms<sup>(7)</sup>

### ***AF/Other***

#### ***Atrial Fibrillation ~~while awake~~(AF)/Other***<sup>(6,7,9)</sup>

- AF, with pauses ≥ 5 seconds while awake, or symptomatic bradycardia<sup>(6)</sup>
- In sinus rhythm (with AV block) while awake, pauses ≥ 3 seconds or heart rates less than rate < 40 beats per minute bpm or an escape rhythm below the AV node<sup>(6)</sup>
- Following catheter ablation of the AV junction<sup>(6)</sup>
- Symptomatic AV block that results from required medical therapy for which there is no alternative treatment<sup>(6,7)</sup>
- Exercise-induced second- or third-degree AV block without myocardial ischemia<sup>(6,7)</sup>
- With slow ventricular response and LVEF < 50% (AUC SCORE 7)

### ***Neuromuscular Disorders***<sup>(6,7)</sup>

- Marked first-degree or higher AV block, or an H-V (His-ventricular) interval ≥ 70 ms, associated with neuromuscular diseases, such as myotonic muscular dystrophy, Erb's dystrophy, Kearns-Sayre syndrome, and peroneal muscular atrophy, regardless of symptoms<sup>(6,7)</sup>

### ***Chronic Fascicular (~~Including Any of~~ Block\*)***<sup>(6,7,10)</sup>

\*includes right bundle branch (RBBB-), left bundle branch (LBBB-), left anterior hemi (LAHB-), and left posterior hemi (LPHB) block

- Alternating bundle-branch block<sup>(6,7)</sup>

- ~~Syncope of unexplained origin when other likely causes have been excluded, specifically ventricular tachycardia<sup>(6)</sup>~~
- Syncope and bundle branch block with an HVH-V interval  $\geq$  70 ms, or evidence of infranodal block at EPS<sup>(7)</sup>
- Incidental findings at EPS study of an H-V interval  $\geq$  100 milliseconds, or non-physiological, pacing-induced infra-His block in asymptomatic patients <sup>(6)</sup>Hypersensitive Carotid Sinus Syndrome And Neurocardiogenic Syncope

## ~~Hypersensitive Carotid Sinus Syndrome And Neurocardiogenic Syncope~~

- Recurrent syncope due to spontaneously occurring carotid sinus stimulation AND carotid sinus pressure induced ventricular asystole  $\geq$  3 seconds<sup>(6)</sup>, or AV block, or  $\geq$  50 mmHg drop in systolic blood pressure (BP)
- Syncope without clear, provocative events and with a hypersensitive cardioinhibitory response (asystole)  $\geq$  3 seconds<sup>(6)</sup>
- Recurrent syncope and asystole  $\geq$  3 seconds with syncope or  $\geq$  6 seconds without symptoms or with presyncope, documented by ECG recording data<sup>(9,10)</sup>

## **Pacing to Terminate or Prevent Tachycardia<sup>(6)</sup>**

- Symptomatic recurrent supraventricular tachycardia documented to be terminated by pacing in the setting of failed catheter ablation and/or drug treatment<sup>(6)</sup>
- Prevention of pause-dependent ventricular tachycardia (VT)<sup>(6)</sup>

## ~~Recommendations for Permanent Pacing in Patients with Hypertrophic Cardiomyopathy (HCM)~~<sup>(6)</sup>

- Permanent pacing may be considered in medically refractory symptomatic patients with HCM and significant resting or provoked left ventricle (LV) outflow tract obstruction

## ~~Recommendations for Leadless Pacemaker Include<sup>(11,12)</sup> Pacemakers<sup>(9)</sup>~~

- ~~Patients with bradycardia and need only single chamber (RV) pacing in VVI or VVIR mode:~~
  - ~~Symptomatic paroxysmal or permanent high-grade AV block in the presence of atrial fibrillation (AF).~~

Symptomatic paroxysmal Leadless pacemakers can only provide ventricular pacing but have fewer complications than transvenous pacemakers. Therefore, permanent pacing via leadless pacemaker is indicated for patients with nonreversible symptomatic bradycardia who are not eligible for an implantable cardioverter defibrillator (ICD), and have one or more of the following:

- No upper extremity access and left ventricular ejection fraction (LVEF) > 50% (**AUC SCORE 7**)
  - Long-standing persistent or permanent high-grade AV block in the absence of AF, as an alternative to dual chamber pacing, AF and normal LVEF, when atrial lead placement is considered difficult, high-risk, or not deemed necessary for effective therapy.
  - Symptomatic bradycardia-tachycardia syndrome or sinus node dysfunction (sinus bradycardia or sinus pauses), as an alternative to atrial or dual chamber pacing, when atrial lead placement is considered difficult, high-risk, or not deemed necessary, the longevity of the device is anticipated to be greater than patient survival, and the need for effective therapy.
- Rate-responsive pacing is indicated to provide increased heart rate appropriate to increasing levels of activity anticipated as < 40% (**AUC SCORE 7**)
- History of multiple cardiovascular implantable electronic device (CIED) infections, LVEF > 50% and need for pacing anticipated as < 40% (**AUC SCORE 7**)
- AV junction ablation and long-standing persistent/permanent AF, LVEF > 50% (**AUC SCORE 7**)
- Pre-existing subcutaneous ICD and need for pacing anticipated as < 40%
  - LVEF > 50% and persistent/permanent AF (**AUC SCORE 7**) OR
  - Paroxysmal AF (**AUC SCORE 7**)

## **INDICATIONS FOR ~~CONGENITAL HEART DISEASE~~ PACING (PEDIATRIC AND ADULT)**

### **CHILDREN, ADOLESCENTS (<19 YEARS), AND ADULT PATIENTS WITH CONGENITAL HEART DISEASE (CHD)**

## **Sinus Node Dysfunction** (7,11)

- SND with symptomatic age- and activity-inappropriate bradycardia<sup>(7)</sup>
- Sinus bradycardia with complex CHD AND a resting heart rate < 40 bpm **OR** pauses in ventricular rate > 3 seconds<sup>(13)</sup>
- CHD and impaired hemodynamics due to sinus bradycardia or loss of AV synchrony
- Asymptomatic sinus bradycardia following repair of CHD with an awake resting heart rate < 40 bpm or pauses in ventricular rate > 3 seconds
- CHD and SND or junctional bradycardia, for the prevention of recurrent episodes of intra-atrial reentrant tachycardia

## **AV Block** (6–8)

- Second- or third-degree AV block with symptomatic bradycardia, ventricular dysfunction, or low cardiac output<sup>(8)</sup>
- Congenital third-degree AV block with a wide QRS escape rhythm, complex ventricular ectopy, or ventricular dysfunction<sup>(7)</sup>
- Postoperative advanced second- or third-degree AV block that is not expected to resolve or that persists at least 7 days after cardiac surgery
- Congenital third-degree AV block in the infant with a ventricular rate < 55 bpm or with congenital heart disease and a ventricular rate < 70 bpm
- Congenital third-degree AV block after 1 year of age with an average heart rate < 50 bpm, abrupt pauses in ventricular rate that are 2 or 3 times the basic cycle length, or associated with symptoms due to chronotropic incompetence<sup>(7)</sup>
- Adults with congenital complete AV block with symptomatic bradycardia, wide QRS escape rhythm, mean daytime heart rate < 50 bpm, complex ventricular ectopy, or ventricular dysfunction<sup>(7,8)</sup>
- Adults with congenital complete AV block, regardless of symptoms<sup>(7)</sup>
- Unexplained syncope after prior congenital heart surgery complicated by transient complete heart block, with residual fascicular block after excluding other causes of syncope
- Congenital third-degree AV block in asymptomatic children or adolescents with an acceptable rate, a narrow QRS, and normal ventricular function

## ~~Scenarios in which Pacemakers are Not Indicated~~<sup>(8,14)</sup>

- ~~SND in patients that are asymptomatic, or symptoms occur without documented bradycardia~~
- ~~Asymptomatic first-degree AV block or Mobitz I second-degree AV block with a narrow QRS~~
- ~~Asymptomatic fascicular block (Including any of RBBB, LBBB, LAHB, LPHB)~~
- ~~Asymptomatic bifascicular block (RBBB/LAHB or RBBB/LPHB) with or without first-degree AVB where a higher degree of heart block has not been demonstrated~~
- ~~Hypersensitive cardioinhibitory response to carotid sinus stimulation without symptoms or with vague symptoms~~
- ~~Asymptomatic bifascicular block (RBBB/LAHB or RBBB/LPHB) with or without first-degree AVB after surgery for CHD without prior transient complete AV block~~

## CODING AND STANDARDS

### **Coding**

### **CPT Codes**

33206, 33207, 33208, 33212, 33213, 33215, 33216, 33217, 33218, 33220, 33274, 33275

## Applicable Lines of Business

<input checked="" type="checkbox"/>	CHIP (Children's Health Insurance Program)
<input checked="" type="checkbox"/>	Commercial
<input checked="" type="checkbox"/>	Exchange/Marketplace
<input checked="" type="checkbox"/>	Medicaid
<input checked="" type="checkbox"/>	Medicare Advantage

## BACKGROUND

A pacemaker system is composed of a pulse generator and one or more leads. The pulse generator is implanted under the skin, usually below one of the collarbones (clavicles). It contains a battery, a microprocessor that governs timing and function, and a radio antenna to allow for noninvasive interrogation and reprogramming. The leads are insulated cables that conduct electricity from the pulse generator to the heart. Leads are most commonly inserted into a vein and then advanced under fluoroscopy (x-ray guidance) to within one or more heart chambers. The leads are fastened within the chambers to the heart muscle using either hooks or retractable/extendable screws, which are built into their tips. Timed electrical impulses are delivered from the pulse generator via the leads to the heart, where stimulation results in heart muscle contraction.

## AUC Score

A reasonable diagnostic or therapeutic procedure care can be defined as that for which the expected clinical benefits outweigh the associated risks, enhancing patient care and health outcomes in a cost-effective manner.<sup>(4)</sup> <sup>(2)</sup>

- *Appropriate Care* - Median Score 7-9
- *May be Appropriate Care* - Median Score 4-6
- *Rarely Appropriate Care* - Median Score 1-3

## Heart Block Definitions (6)

- First-Degree: All sinus or atrial beats are conducted to the ventricles, but with a delay (PR interval of > 200 ms)
- Second-Degree: Intermittent failure of conduction of single beats from atrium to ventricles
  - (Mobitz) Type I: Conducted beats have variable conduction times from atrium to ventricles
  - (Mobitz) Type II: Conducted beats have uniform conduction times from atrium to ventricles
  - Advanced or high degree: Two or more consecutive non-conducted sinus or (non-premature) atrial beats with some conducted beats
- Third-Degree: No atrial beats are conducted from atrium to ventricle

## Acronyms / Abbreviations

AV: Atrioventricular

BP: blood pressure

BPM: beats per minute

CHF: Congestive heart failure

CRT: Cardiac resynchronization therapy (same as biventricular pacing)

ECG: Electrocardiogram

EPS: Electrophysiologic Study

GDMT: Guideline-Directed Medical Therapy

HVHCM: Hypertrophic cardiomyopathy

H-V: His-ventricular

ICD: Implantable cardioverter-defibrillator

LAHB: Left Anterior Hemiblock

LBBB: Left bundle-branch block

LPHB: Left Posterior Hemiblock

LV: Left ventricular/left ventricle

LVEF: Left ventricular ejection fraction

MI: Myocardial infarction

ms: Milliseconds

RBBB: Right Bundle Branch Block

s: Seconds

STEMI: ST-elevation Myocardial Infarction

SND: Sinus node dysfunction

VT: Ventricular tachycardia

## **SUMMARY OF EVIDENCE**

**2012 ACCF/AHA/HRS focused update incorporated into the ACCF/AHA/HRS 2008 guidelines for device-based therapy of cardiac rhythm abnormalities**<sup>(6)</sup>

**Study Design:** This document is a guideline developed by the American Heart Association/American College of Cardiology Joint Committee on Clinical Practice Guidelines, in collaboration with several other medical societies. It includes recommendations based on a comprehensive literature search and evidence review.

**Target Population:** The guidelines focus on patients with hypertrophic cardiomyopathy, including adults, children, and adolescents. It addresses the diagnosis, risk assessment, and management of HCM, including the use of ICDs for SCD prevention.

### **Key Factors**

- **Risk Assessment:** The document highlights the importance of SCD risk assessment in HCM patients, including factors such as family history of SCD, maximal LV wall thickness, unexplained syncope, LV apical aneurysm, extensive LGE, and NSVT episodes.
- **ICD Placement:** Recommendations for ICD placement in high-risk HCM patients consider individual clinical judgment, shared decision-making, and the presence of major risk factors.
- **Device Selection:** The guidelines discuss the selection of ICD devices, including single-chamber, dual-chamber, and subcutaneous ICDs, based on patient preferences and clinical needs.
- **Management:** The document provides recommendations for the pharmacological and invasive treatment of symptomatic HCM patients, including the use of beta blockers, calcium channel blockers, myosin inhibitors, and septal reduction therapies.

### **2018 ACC/AHA/HRS Guideline on the Evaluation and Management of Patients with Bradycardia and Cardiac Conduction Delay**<sup>(7)</sup>

**Study Design:** This document is a guideline developed by the American College of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines and the Heart Rhythm Society, in collaboration with several other medical societies. It includes recommendations based on a comprehensive literature search and evidence review.

**Target Population:** The guidelines focus on patients with bradycardia and cardiac conduction delay, including adults with sinus node dysfunction (SND), atrioventricular (AV) block, and other conduction disorders. It addresses the diagnosis, risk assessment, and management of these conditions.

### **Key Factors**

- **Risk Assessment:** The document emphasizes the importance of identifying reversible causes of bradycardia and conduction delay, such as medications, electrolyte imbalances, and underlying medical conditions.
- **Device Selection:** Recommendations for pacemaker implantation consider patient preferences, age, lifestyle, and clinical needs.
- **Management:** The guidelines provide recommendations for the acute and chronic management of bradycardia and conduction delay, including the use of temporary and permanent pacing.

## ACC/AHA/ASE/HFSA/HRS/SCAI/SCCT/SCMR 2025 Appropriate Use Criteria for Implantable Cardioverter-Defibrillators, Cardiac Resynchronization Therapy, and Pacing<sup>(9)</sup>

**Study Design:** The study involved the development of Appropriate Use Criteria (AUC) for ICDs, cardiac resynchronization therapy (CRT), and pacing. The process included drafting clinical scenarios based on patient presentations encountered in everyday practice. These scenarios were evaluated by an independent rating panel using a scoring scale from 1 to 9.

**Target Population:** The study focused on patients who may require ICDs, CRT, or pacing therapies. This includes patients with coronary artery disease (CAD), nonischemic cardiomyopathy (CM), genetic arrhythmia diseases, heart failure (HF), and those with left ventricular assist devices (LVADs).

### **Key Factors:**

- **Clinical Scenarios:** The scenarios included information on symptom status, risk level as assessed by noninvasive testing, coronary disease burden, and in some cases, fractional flow reserve testing, presence or absence of diabetes, and SYNTAX score.
- **Scoring:** Each indication was scored as "Appropriate" (7 to 9), "May Be Appropriate" (4 to 6), or "Rarely Appropriate" (1 to 3).
- **Therapy Options:** The study evaluated the appropriateness of ICDs, CRT, and pacing therapies for various clinical scenarios.
- **Emphasis:** The study emphasized the importance of guideline-directed medical therapy and antianginal therapy in the management of patients.
- **Patient Preference:** The study highlighted the role of shared decision-making and patient preferences in the selection of therapy options.

## **ANALYSIS OF EVIDENCE**

### **Shared Conclusions**

All three articles emphasize the importance of evidence-based practice and provide detailed guidelines for pacemaker implantation based on clinical evidence. They all address specific conditions requiring pacing and offer recommendations for the evaluation and management of patients with bradycardia and conduction disorders. Additionally, they highlight the importance of correlating symptoms with bradycardia and conduction disorders to ensure appropriate management.

In summary, these articles collectively provide a comprehensive understanding of pacemaker implantation, highlighting the importance of evidence-based practice, detailed evaluation, and management of bradycardia and conduction disorders, while also addressing specific conditions and emphasizing patient-centered care.

## POLICY HISTORY

Date	Summary
<u>July 2025</u>	<ul style="list-style-type: none"> <li>Reviewed to reconcile dates, no substantive changes made</li> </ul>
<u>June 2025</u>	<ul style="list-style-type: none"> <li>Added third bullet to General Information</li> <li>Added Summary of Evidence and Analysis of Evidence</li> <li>This guideline merges two Evolent guidelines with identical clinical criteria: ECG 7315-01 for Pacemaker Implantation and ECG 322 for Pacemaker <ul style="list-style-type: none"> <li>This guideline also merges procedural codes</li> </ul> </li> <li>Guideline name changed to Pacemaker Insertion</li> </ul>
<u>April 2025</u>	<ul style="list-style-type: none"> <li>Guideline number changed to 7315</li> <li>Updated citations</li> <li>Updated indications for leadless pacemakers</li> <li>Updated indications for chronic fascicular block</li> <li>Removed Contraindications</li> <li>Reduced Background</li> </ul>
<u>March 2024</u>	<ul style="list-style-type: none"> <li>Added AUC Scoring to Cardiac Guidelines from published Societies. When an AUC score was not published by a Society, we assigned an AUC score of 6 based upon AUC scoring standards—this has been explained in Clinical Reasoning</li> </ul>

### ***Summary***

## LEGAL AND COMPLIANCE

### **Guideline Approval**

#### **Committee**

Reviewed / Approved by Evolent Specialty Services Clinical Guideline Review Committee



## Disclaimer

*Evolent Clinical Guidelines do not constitute medical advice. Treating health care professionals are solely responsible for diagnosis, treatment, and medical advice. Evolent uses Clinical Guidelines in accordance with its contractual obligations to provide utilization management. Coverage for services varies for individual members according to the terms of their health care coverage or government program. Individual members' health care coverage may not utilize some Evolent Clinical Guidelines. Evolent clinical guidelines contain guidance that requires prior authorization and service limitations. A list of procedure codes, services or drugs may not be all inclusive and does not imply that a service or drug is a covered or non-covered service or drug. Evolent reserves the right to review and update this Clinical Guideline in its sole discretion. Notice of any changes shall be provided as required by applicable provider agreements and laws or regulations. Members should contact their Plan customer service representative for specific coverage information.*

*Evolent Clinical Guidelines are comprehensive and inclusive of various procedural applications for each service type. Our guidelines may be used to supplement Medicare criteria when such criteria is not fully established. When Medicare criteria is determined to not be fully established, we only reference the relevant portion of the corresponding Evolent Clinical Guideline that is applicable to the specific service or item requested in order to determine medical necessity.*

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