

<b>*Evolut</b>	
<b>Clinical guidelines PACEMAKER</b>	<b>Original Date: February 2013</b>
<b>CPT Codes: 33206, 33207, 33208, 33212, 33213, 33214, 33227, 33228</b>	<b>Last Revised Date: April 2023</b>
<b>Guideline Number: Evolut_CG_322</b>	<b>Implementation Date: January 2024</b>

**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.*

**INDICATIONS FOR PACEMAKERS – ADULT (Excludes conditions that are expected to resolve)<sup>1, 2</sup>**

**Sinus Node Dysfunction (SND)**

- Documented symptomatic sinus bradycardia, including frequent sinus pauses
- 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
- Symptomatic sinus bradycardia that results from required guideline-directed medical therapy (GDMT) for which there is no alternative treatment
- Heart rate less than 40 while awake, even without definite association with significant symptoms consistent with bradycardia
- Tachycardia-bradycardia syndrome and symptoms attributable to bradycardia<sup>2</sup>
- Syncope of unexplained origin with clinically significant SND, either documented or provoked in electrophysiologic study (EPS)

**Acquired Atrioventricular (AV) Block**

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

- Marked first-degree Mobitz Type 1 AV block with symptoms clearly attributable to the AV block
- First-degree AV block with “pacemaker syndrome” symptoms (chronic fatigue, dyspnea on exertion, symptomatic hypotension) or hemodynamic compromise

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

- Marked second-degree Mobitz Type 1 AV block with symptoms clearly attributable to the AV block
- Second-degree AV block with “pacemaker syndrome” symptoms (chronic fatigue, dyspnea on exertion, symptomatic hypotension) or hemodynamic compromise
- Second-degree Mobitz Type II AV block regardless of symptoms
- Advanced second-degree AV block
- Second-degree AV block associated with a wide QRS, or EPS-documented intra- or infra-His conduction
- Symptomatic bradycardia associated with second-degree AV block, either Mobitz I or II

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

- Third-degree (complete) AV block, intermittent or persistent, regardless of symptoms
- High-grade AV block, regardless of symptoms

### **AF/Other**

- Atrial fibrillation while awake, with pauses  $\geq 5$  seconds, or symptomatic bradycardia
- In sinus rhythm (with AV block) while awake, pauses  $\geq 3$  seconds or heart rates less than 40 beats per minute or an escape rhythm below the AV node
- Following catheter ablation of the AV junction
- Symptomatic AV block that results from required medical therapy for which there is no alternative treatment
- Exercise-induced second- or third-degree AV block without myocardial ischemia

### **Neuromuscular Disorders**

- Marked first-degree or higher AV block, or an H-V interval  $\geq 70$  ms, associated with neuromuscular diseases, such as myotonic muscular dystrophy, Erb’s dystrophy, Kearns-Sayre syndrome, and peroneal muscular atrophy, regardless of symptoms

### **Chronic Fascicular (Including any of RBBB, LBBB, LAHB, LPHB) Block**

- Alternating bundle-branch block
- Syncope of unexplained origin when other likely causes have been excluded, specifically ventricular tachycardia<sup>3</sup>

- Syncope and bundle branch block with an HV interval  $\geq 70$  ms, or evidence of infranodal block at EPS<sup>2</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

### **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, or AV block, or  $\geq 50$  mmHg drop in systolic BP<sup>1, 3</sup>
- Syncope without clear, provocative events and with a hypersensitive cardioinhibitory response (asystole)  $\geq 3$  seconds
- Recurrent syncope and asystole  $\geq 3$  seconds with syncope or  $\geq 6$  seconds without symptoms or with presyncope, documented by ECG recording data<sup>4, 5</sup>

### **Pacing to Terminate or Prevent Tachycardia**

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

## **INDICATIONS FOR PEDIATRIC AND ADULT CONGENITAL HEART DISEASE PACING<sup>1, 4, 6</sup>**

### **Children, Adolescents (< 19 years), and ADULT Patients with Congenital Heart Disease (CHD)**

#### **Sinus Node Dysfunction (SND)**

- SND with symptomatic age- and activity-inappropriate bradycardia
- Sinus bradycardia with complex CHD AND a resting heart rate  $< 40$  bpm **OR** pauses in ventricular rate  $> 3$  seconds
- 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<sup>4, 6, 7</sup>

#### **AV Block**

- Second- or third-degree AV block with symptomatic bradycardia, ventricular dysfunction, or low cardiac output
- Congenital third-degree AV block with a wide QRS escape rhythm, complex ventricular ectopy, or ventricular dysfunction
- 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
- 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>2</sup>
- Adults with congenital complete AV block, regardless of symptoms<sup>2</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**

- 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

---

## **BACKGROUND<sup>1</sup>**

Pacemaker implantation generally serves to address bradycardia, with the intention of ameliorating related symptoms, preventing complications of syncope, and/or reducing mortality risk.

This guideline is not intended to cover the type of bradycardia pacing device. CRT (cardiac resynchronization therapy or biventricular pacing) and ICD (implantable cardioverter defibrillator) implantation are covered in separate guidelines.

## **OVERVIEW**

### **General**

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.

Leadless pacemakers are sometimes used as an alternative to transvenous pacemakers when no upper extremity venous access exists or when risk of device pocket infection is particularly high, such as previous infection and patients on hemodialysis.<sup>8</sup> Leadless pacemakers currently only have the capacity to pace the ventricle. The prevalence of leadless device infections is low as the principal source of infection.

### **Heart Block Definitions<sup>1</sup>**

- 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

## Abbreviations

AV	Atrioventricular
CHF	Congestive heart failure
CRT	Cardiac resynchronization therapy (same as biventricular pacing)
ECG	Electrocardiogram
EPS	Electrophysiologic Study
GDMT	Guideline-Directed Medical Therapy
HV	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

## REFERENCES

1. Epstein AE, DiMarco JP, Ellenbogen KA, et al. 2012 ACCF/AHA/HRS focused update incorporated into the ACCF/AHA/HRS 2008 guidelines for device-based therapy of cardiac rhythm abnormalities: a report of the American College of Cardiology Foundation/American Heart Association Task Force on Practice Guidelines and the Heart Rhythm Society. *Circulation*. Jan 22 2013;127(3):e283-352. doi:10.1161/CIR.0b013e318276ce9b
2. Kusumoto FM, Schoenfeld MH, Barrett C, et al. 2018 ACC/AHA/HRS Guideline on the Evaluation and Management of Patients With Bradycardia and Cardiac Conduction Delay: A Report of the American College of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines and the Heart Rhythm Society. *J Am Coll Cardiol*. Aug 20 2019;74(7):e51-e156. doi:10.1016/j.jacc.2018.10.044
3. Shen WK, Sheldon RS, Benditt DG, et al. 2017 ACC/AHA/HRS Guideline for the Evaluation and Management of Patients With Syncope: A Report of the American College of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines and the Heart Rhythm Society. *Circulation*. Aug 1 2017;136(5):e60-e122. doi:10.1161/cir.000000000000499
4. Brignole M, Menozzi C, Moya A, et al. Pacemaker therapy in patients with neurally mediated syncope and documented asystole: Third International Study on Syncope of Uncertain Etiology (ISSUE-3): a randomized trial. *Circulation*. May 29 2012;125(21):2566-71. doi:10.1161/circulationaha.111.082313
5. Varosy PD, Chen LY, Miller AL, Noseworthy PA, Slotwiner DJ, Thiruganasambandamoorthy V. Pacing as a Treatment for Reflex-Mediated (Vasovagal, Situational, or Carotid Sinus Hypersensitivity) Syncope: A Systematic Review for the 2017 ACC/AHA/HRS Guideline for the Evaluation and Management of Patients With Syncope: A Report of the American College of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines and the Heart Rhythm Society. *Circulation*. Aug 1 2017;136(5):e123-e135. doi:10.1161/cir.000000000000500
6. Brugada J, Blom N, Sarquella-Brugada G, et al. Pharmacological and non-pharmacological therapy for arrhythmias in the pediatric population: EHRA and AEPC-Arrhythmia Working Group joint consensus statement. *Europace*. Sep 2013;15(9):1337-82. doi:10.1093/europace/eut082
7. Khairy P, Van Hare GF, Balaji S, et al. PACES/HRS Expert Consensus Statement on the Recognition and Management of Arrhythmias in Adult Congenital Heart Disease: developed in partnership between the Pediatric and Congenital Electrophysiology Society (PACES) and the Heart Rhythm Society (HRS). Endorsed by the governing bodies of PACES, HRS, the American College of Cardiology (ACC), the American Heart Association (AHA), the European Heart Rhythm Association (EHRA), the Canadian Heart Rhythm Society (CHRS), and the International Society for Adult Congenital Heart Disease (ISACHD). *Heart Rhythm*. Oct 2014;11(10):e102-65. doi:10.1016/j.hrthm.2014.05.009
8. Glikson M, Nielsen JC, Kronborg MB, et al. 2021 ESC Guidelines on cardiac pacing and cardiac resynchronization therapy: Developed by the Task Force on cardiac pacing and cardiac resynchronization therapy of the European Society of Cardiology (ESC) With the special contribution of the European Heart Rhythm Association (EHRA). *European Heart Journal*. 2021;42(35):3427-3520. doi:10.1093/eurheartj/ehab364

## POLICY HISTORY

Date	Summary
April 2023	<ul style="list-style-type: none"><li>• Additional statement on leadless pacemaker</li><li>• Added statement on clinical indications not addressed in this guideline</li></ul>
February 2022	<ul style="list-style-type: none"><li>• Added section on leadless pacemakers</li></ul>



## Reviewed / Approved by Clinical Guideline Committee

**Disclaimer:** *Evolut Clinical Guidelines do not constitute medical advice. Treating health care professionals are solely responsible for diagnosis, treatment and medical advice. Evolut 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 Evolut Clinical Guidelines. 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. Evolut 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.***