



Magellan Healthcare	
Clinical guidelines PACEMAKER	Original Date: February, 2013 Page 1 of 9
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INTRODUCTION

Pacemakers are implantable devices used to treat bradycardia, certain tachycardias and occasionally certain cardiomyopathies. Dual chamber devices are helpful for many of patients in improving quality of life and congestive heart failure. Many patients with dilated cardiomyopathy receive implantable defibrillators with cardiac resynchronization therapy (CRT) capability. However, CRT requires separate authorization as CRT has specific criteria.

Appropriate use criteria have not been established for pacemaker insertion. Clinicians rely upon ACC/AHA/HRS guidelines, which were updated for bradycardia indications in 2008. A focused guideline update was published in 2012, which considered left ventricular ejection fraction (LVEF), QRS pattern, QRS duration, and consideration regarding the presence of atrial fibrillation in its differentiation between classes, I, IIa, and IIb indications.

Initial Clinical Reviewers (ICRs) and Physician Clinical Reviewers (PCRs) must be able to apply criteria based on individual needs and based on an assessment of the local delivery system.

INDICATIONS AND CONTRAINDICATIONS FOR PACEMAKERS BY CONDITION

- **Indications for Sinus Node Dysfunction:**
 - Symptomatic bradycardia (< 60 bpm), which includes syncope, near-syncope, dizziness, lethargy, congestive heart failure (CHF), fatigue, or dyspnea, whether spontaneous or as a result of clinically indicated medications or procedures (e.g. medical or catheter treatment for atrial fibrillation) that intentionally slow the heart rate, documented by EKG or telemetry.
 - Symptomatic heart beat pauses, documented by EKG or telemetry.
 - Symptomatic chronotropic incompetence, documented by stress test or telemetry.
 - Heart rate less than 40 with symptoms consistent with bradycardia.
 - Heart rate less than 40 observed in the waking state without clear association between symptoms and heart rate.
 - Syncope with electrophysiologic study (EPS) findings of abnormal sinus node function.

- **Contraindications for Sinus Node Dysfunction:**
 - Asymptomatic.
 - Symptoms in the absence of bradycardia.
 - Bradycardia resulting from nonessential drug therapy.

- **Indications for Acquired Third-Degree and Advanced Second-Degree Atrioventricular (AV) Block:**
 - Persistent third-degree atrioventricular block, with or without symptoms
 - In atrial fibrillation and while awake, pauses in heartbeat ≥ 5 seconds with or without symptoms.
 - In sinus rhythm and while awake, pauses in heartbeat ≥ 3 seconds or heart rates less than 40 beats per minute or an escape rhythm below the AV node, with or without symptoms.
 - Following catheter ablation of the AV junction.
 - Following cardiac surgery, if expected to be permanent.
 - In neuromuscular diseases such as myotonic muscular dystrophy, Erb dystrophy (limb-girdle muscular dystrophy), Kearns-Sayre syndrome, and peroneal muscular atrophy.
 - Exercise-induced heart block without myocardial ischemia.

- **Contraindications for Acquired Third-Degree and Advanced Second-Degree Atrioventricular Block:**
 - AV block is expected to resolve and is unlikely to recur (e.g. drug toxicity, Lyme disease, or transient increases in vagal tone or during hypoxia in sleep apnea syndrome) and without symptoms.
 - AV block secondary to nonessential drug therapy.

- **Indications for Other Presentations of First- and Second-Degree AV Block:**
 - Symptomatic second-degree AV block.
 - Type II second-degree AV block, with or without symptoms.
 - Second-degree AV block due to EP-documented intra- or infra-His levels.
 - First- or second-degree AV block with “pacemaker syndrome” symptoms or hemodynamic compromise (i.e. hypotension, syncope and pulmonary edema).
 - In neuromuscular diseases such as myotonic muscular dystrophy, Erb dystrophy (limb-girdle muscular dystrophy), Kearns-Sayre syndrome, and peroneal muscular atrophy.
 - AV block due to drug use and/or drug toxicity AND block is expected to recur after drug withdrawal.
 - Exercise-induced second degree heart block without myocardial ischemia.

- **Contraindications for Other Presentations of First- and Second-Degree AV Block:**
 - AV block is expected to resolve and is unlikely to recur (e.g. drug toxicity, Lyme disease, or transient increases in vagal tone or during hypoxia in sleep apnea syndrome) and without symptoms.
 - AV Block secondary to nonessential drug therapy.

- **Indication for Permanent Pacing for Chronic Bifascicular Block:**
 - Type II second-degree AV block, advanced second-degree AV block (see definitions section) or intermittent third-degree AV block.

- Alternating bundle-branch block.
- Syncope and bifascicular block when other likely causes have been excluded, specifically ventricular tachycardia.
- Electrophysiologic study (EPS) documentation of an H-V interval ≥ 100 milliseconds, even in asymptomatic patients.
- Electrophysiologic study (EPS) documentation of non-physiological, pacing-induced infra-His block.
- In neuromuscular diseases such as myotonic muscular dystrophy, Erb dystrophy (limb-girdle muscular dystrophy), and peroneal muscular atrophy with bifascicular block or any fascicular block.

Contraindications for Permanent Pacing for Chronic Bifascicular Block:

- Asymptomatic fascicular block without AV block.
- Asymptomatic fascicular block with first-degree AV block.

● **Indication for Permanent Pacing After the Acute Phase of Myocardial Infarction:**

- Persistent second- or third-degree AV block after ST-elevation Myocardial Infarction (STEMI).
- Transient second- or third-degree AV block below the AV node after STEMI. If the site of block is uncertain, electrophysiologic study (EPS) may be necessary.

Contraindications for Permanent Pacing After the Acute Phase of Myocardial Infarction:

- Bradycardia secondary to nonessential drug therapy.
- Transient AV block without intraventricular conduction defects.
- Transient AV block with isolated left anterior fascicular block.
- New bundle-branch block or fascicular block without AV block.
- Asymptomatic first-degree AV block with bundle-branch or fascicular block.

● **Indication for Permanent Pacing in Hypersensitive Carotid Sinus Syndrome and Neurocardiogenic Syncope:**

- Recurrent syncope due to spontaneously occurring carotid sinus stimulation AND carotid sinus pressure induces ventricular asystole ≥ 3 seconds.
- Syncope without clear, provocative events and with a hypersensitive cardioinhibitory response (asystole) of 3 seconds or longer.
- Neurocardiogenic syncope associated with bradycardia occurring spontaneously or at the time of tilt-table testing.

Contraindications for Permanent Pacing in Hypersensitive Carotid Sinus Syndrome and Neurocardiogenic Syncope:

- Hypersensitive cardioinhibitory response to carotid sinus stimulation without symptoms or with vague symptoms.
- Situational neurocardiogenic syncope in which avoidance behavior is effective and preferred.

● **Indication following Cardiac Transplantation:**

- Persistent inappropriate or symptomatic bradycardia not expected to resolve and for all other indications for permanent pacing.

- Prolonged bradycardia limiting rehabilitation or discharge.
- Syncope after transplantation even when bradyarrhythmia has not been documented.

Contraindications for Pacing following Cardiac Transplantation:

- Bradycardia secondary to nonessential drug therapy.

- **Indication for Permanent Pacemakers That Automatically Detect and Pace to Terminate Tachycardia:**

- Symptomatic recurrent supraventricular tachycardia documented to be pacing terminated in the setting of failed catheter ablation and/or drug treatment or intolerance.

Contraindications for Permanent Pacemakers That Automatically Detect and Pace to Terminate Tachycardia:

- Presence of an accessory pathway with capacity for rapid anterograde conduction.

- **Indication for Pacing to Prevent Tachycardia:**

- Sustained pause-dependent Ventricular tachycardia (VT), with or without QT prolongation.
- High-risk congenital long-QT syndrome.
- Symptomatic, drug-refractory, recurrent atrial fibrillation in patients with coexisting Sinus Node Dysfunction (SND), when the record documents that the patient has either failed atrial fibrillation ablation or is not considered a candidate for a specified reason.

Contraindications for Pacing to Prevent Tachycardia:

- Ventricular ectopic without sustained VT in the absence of the long-QT syndrome.
- Reversible, e.g., drug-related, Torsade de pointes VT.

- **Indication for Pacing in Patients with Hypertrophic Cardiomyopathy:**

- Symptomatic hypertrophic cardiomyopathy and hemodynamically significant resting or provoked LV outflow tract obstruction AND refractory to medical therapy.

Contraindications for Pacing in Patients with Hypertrophic Cardiomyopathy:

- Asymptomatic OR symptoms controlled on medical therapy.
- Without significant LV outflow tract obstruction.

- **Indication for Pacing in Children, Adolescents, and Patients with Congenital Heart Disease:**

- Second- or third-degree AV block with symptomatic bradycardia, ventricular dysfunction, or low cardiac output.
- SND with symptoms and age-inappropriate bradycardia. The definition of bradycardia varies with the patient's age and expected heart rate. For normal heart rates by age, please see the table at the end.
- Postoperative advanced second- or third-degree AV block that is expected to be permanent or that persists >7 days after cardiac surgery.
- 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 heart disease and sinus bradycardia for the prevention of recurrent episodes of intra-atrial reentrant tachycardia, either intrinsic or secondary to anti-arrhythmic treatment.
- Congenital third-degree AV block after age 1 year 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.
- Sinus bradycardia with complex congenital heart disease AND a resting heart rate < 40 bpm OR pauses in ventricular rate >3 seconds.
- Congenital heart disease and impaired hemodynamics due to sinus bradycardia or loss of AV synchrony.
- Unexplained syncope after prior congenital heart surgery complicated by transient complete heart block, with residual fascicular block after a careful evaluation to exclude other causes of syncope.
- Transient postoperative third-degree AV block that reverts to sinus rhythm with residual bifascicular block.
- Permanent pacemaker implantation may be considered for congenital third-degree AV block in asymptomatic children or adolescents with an acceptable rate, a narrow QRS complex and normal ventricular function.
- Asymptomatic sinus bradycardia following biventricular repair of congenital heart disease with a resting heart rate < 40 bpm or pauses in ventricular rate > 3 seconds.

Contraindications for Pacing in Children, Adolescents, and Patients with Congenital Heart Disease:

- Asymptomatic transient postoperative AV block with return of normal AV conduction.
- Asymptomatic bifascicular block +/-first-degree AV block after surgery for congenital heart disease in the absence of prior transient complete AV block.
- Asymptomatic type I second-degree AV block.
- Asymptomatic sinus bradycardia with the longest RR interval < 3 seconds and a minimum heart rate > 40 bpm.
- Bradycardia secondary to nonessential drug therapy.

ADDITIONAL INFORMATION:

For Cardiac Resynchronization Pacemaker Implementations, see separate CRT Pacemaker guideline.

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. It contains a battery, a microprocessor that governs timing and function, and a radio antenna to allow for noninvasive 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

sent from the pulse generator down the leads to the heart, where stimulation results in heart muscle contraction.

The most recent guidelines stress that asymptomatic bradycardia rarely qualifies as a class I indication for pacemaker insertion. However, there are some asymptomatic bradycardic rhythms for which pacemaker insertion is indicated because they present a risk of injury or death. In addition, there are also a small number of situations in which the electrocardiogram (EKG) or an invasive electrophysiologic study (EPS) can reveal evidence of specific disease in the cardiac conduction system that warrants pacemaker insertion in the absence of symptoms, for the same reason. Guidelines are fairly specific and technical in these instances.

In the case dilated cardiomyopathy, near-simultaneous stimulation of both ventricles, referred to as cardiac resynchronization therapy (CRT) has been demonstrated to improve cardiac performance and quality of life and to decrease cardiac event rates and mortality among a subset of patients. Device implantation requires the insertion of leads that pace both the right and left ventricles, most commonly with a coronary sinus lead for the LV pacing. The majority of these patients received implantable defibrillators with CRT capability, but pacemakers are sometimes chosen due to patient and physician preference. A focused ACCF/AHA/HRS guideline update was published in 2012, which considered LVEF, QRS pattern, QRS duration, and consideration regarding the presence of atrial fibrillation in its differentiation between classes, I, IIa, and IIb indications. This document will provide criteria for approval of all CRT indications that are presently defined as IIb or stronger.

Current guidelines group pacemaker indications together according to anatomic source and clinical syndromes, and this document follows this approach. Class I through IIb indications are condensed and included as approvable in this document. Generally speaking, for indications that are listed in this summary without reference to symptoms, the presence or absence of symptoms differentiate between class I and II indications.

NYHA Class Definitions:

- Class I: No limitation of functional activity or only at levels of exertion that would limit normal individuals.
- Class II: Slight limitation of activity. Dyspnea and fatigue with moderate exercise.
- Class III: Marked limitation of activity. Dyspnea with minimal activity.
- Class IV: Severe limitation of activity. Symptoms even at rest.

Heart Block Definitions:

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

Abbreviations:

AV = Atrioventricular
 CHF = congestive heart failure
 CRT = Cardiac resynchronization therapy
 EKG = Electrocardiogram
 EPS = Electrophysiologic Study
 GDMT = Guideline-Directed Medical Therapy
 HRS = Heart Rhythm Society
 HV = His-ventricle
 ICD = Implantable cardioverter-defibrillator
 LBBB = left bundle-branch block
 LV = Left ventricular/left ventricle
 LVEF = Left ventricular ejection fraction
 MI = myocardial infarction
 MS = milliseconds
 NYHA = New York Heart Association
 STEMI = ST-elevation Myocardial Infarction
 SND = Sinus node dysfunction
 VT = Ventricular tachycardia

Normal Pediatric Heart Rates: From: www.pediatriccareonline.org/pco/ub/view/Pediatric-Drug-Lookup/153929/0/normal_pediatric_heart_rates

Age	Mean Heart Rate (beats/minute)	Heart Rate Range (2nd – 98th percentile)
<1 d	123	93-154
1-2 d	123	91-159
3-6 d	129	91-166
1-3 wk	148	107-182
1-2 mo	149	121-179
3-5 mo	141	106-186
6-11 mo	134	109-169
1-2 y	119	89-151
3-4 y	108	73-137
5-7 y	100	65-133
8-11 y	91	62-130
12-15 y	85	60-119

Adapted from *The Harriet Lane Handbook*, 12th ed, Greene MG, ed, St Louis, MO: Mosby Yearbook, 1991

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