

<b>National Imaging Associates, Inc.*</b>	
<b>Clinical guidelines</b> <b>PACEMAKER</b>	<b>Original Date: February 2013</b>
<b>CPT Codes:</b> <b>33206, 33207, 33208, 33212, 33213, 33214,</b> <b>33227, 33228</b>	<b>Last Revised Date: March 2021</b>
<b>Guideline Number: NIA_CG_322</b>	<b>Implementation Date: January 2022</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. All prior relevant imaging results, and the reason that alternative imaging cannot be performed must be included in the documentation submitted.

**INDICATIONS FOR PACEMAKERS – ADULT** (Excludes conditions that are expected to resolve) (Epstein, 2013; Kusumoto, 2019)

#### 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 (Kusumoto, 2019)
- 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

---

\* National Imaging Associates, Inc. (NIA) is a subsidiary of Magellan Healthcare, Inc.

- 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 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 (Shen, 2017)
- Syncope and bundle branch block with an HV interval  $\geq 70$  ms, or evidence of infranodal block at EPS (Kusumoto, 2019)
- 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 (Epstein 2013, Shen 2017)
- 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 (Brignole, 2012; Varosy, 2017)

#### **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**

(Brignole, 2013; Brugada, 2013; Epstein, 2013)

#### **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 (Brignole, 2013; Brugada, 2013; Khairy, 2014)

##### **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 (Kusumoto, 2019)
- Adults with congenital complete AV block, regardless of symptoms (Kusumoto, 2019)

- 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**

(Epstein, 2013)

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. Additionally, the Micra transcatheter pacing system is a leadless pacemaker system for indicated patients.

## Heart Block Definitions

(Epstein, 2013)

- 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

## POLICY HISTORY

Date	Summary
March 2021	<ul style="list-style-type: none"> <li>• In Sinus Node Dysfunction section: added Holter/MCOT as acceptable monitoring techniques</li> <li>• In Acquired Atrioventricular (AV) Block section: re-organized section</li> <li>• In Chronic Bifascicular Block section: Changed to 'Bifascicular' to 'Fascicular' and added RBBB, LBBB, LAHB, LPHB</li> <li>• In Pacing to Terminate or Prevent Tachycardia section: changed 'Sustained' to 'Prevention of'</li> <li>• Added 'Adult' to INDICATIONS FOR PEDIATRIC AND CONGENITAL HEART DISEASE PACING</li> <li>• In Scenarios in which Pacemakers are Not Indicated section: <ul style="list-style-type: none"> <li>○ defined and added criteria RBBB/LBBB/LAHB/LPHB/1st degree AVB</li> </ul> </li> <li>• Added Asymptomatic bifascicular block (RBBB/LAHB or RBBB/LPHB) with or without 1st degree AVB where a higher degree of heart block has not been demonstrated</li> </ul>
March 2020	<ul style="list-style-type: none"> <li>• Added general information section as Introduction which outlines requirements for documentation of pertinent office notes by a licensed clinician, and inclusion of laboratory testing and relevant imaging results for case review</li> <li>• Added information regarding a leadless pacemaker system for indicated patients to the Overview section</li> </ul>
July 2019	<ul style="list-style-type: none"> <li>• Added broad definition of chronotropic incompetence</li> <li>• For sinus node dysfunction added indication for tachycardia-bradycardia syndrome "and symptoms attributable to bradycardia"</li> <li>• Indications after the acute phase of myocardial infarction were removed</li> <li>• For hypersensitive carotid sinus syndrome and neurocardiogenic syncope: <ul style="list-style-type: none"> <li>○ Added indication for recurrent syncope and asystole <math>\geq 3</math> seconds with syncope or <math>\geq 6</math> seconds without symptoms or with presyncope, documented by implantable loop recorder</li> <li>○ Removed indication for neurocardiogenic syncope associated with bradycardia occurring spontaneously or at the time of tilt table testing</li> </ul> </li> </ul>

	<ul style="list-style-type: none"> <li>• For hypertrophic cardiomyopathy, removed symptomatic hypertrophic cardiomyopathy and hemodynamically significant resting (peak &gt; 30 mmHg) or provoked (peak &gt; 50 mmHg) LV outflow tract gradient, refractory to medical therapy, and suboptimal candidates for septal reduction therapy (including high risk for developing heart block post procedure)</li> <li>• For pediatric and congenital heart disease pacing, AV block, the following indications were added: <ul style="list-style-type: none"> <li>○ Adults with congenital complete AV block with symptomatic bradycardia, wide QRS escape rhythm, mean daytime heart rate &lt; 50 bpm, complex ventricular ectopy, or ventricular dysfunction</li> <li>○ Adults with congenital complete AV block, regardless of symptoms</li> </ul> </li> <li>• For pediatric and congenital heart disease pacing, AV block, removed postoperative advanced second- or third-degree AV block that is expected to be permanent or that persists ≥ 7 days after cardiac surgery; and transient postoperative third degree AV block that reverts to sinus rhythm with residual bifascicular block</li> <li>• For pediatric and congenital heart disease pacing, scenarios in which pacemakers are not indicated, the following were added: <ul style="list-style-type: none"> <li>○ Asymptomatic first-degree AV block or Mobitz I second-degree AV block with a narrow QRS</li> <li>○ Asymptomatic fascicular block (left anterior or posterior fascicular block)</li> <li>○ Hypersensitive cardioinhibitory response to carotid sinus stimulation without symptoms or with vague symptoms</li> </ul> </li> </ul>
--	---

## REFERENCES

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*. 2012; 125(21):2566-71.

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*. 2013; 15:1337–1382.

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*. 2013; 127L: e283-e352. Available at: <http://circ.ahajournals.org/content/127/3/e283>

Fleming S, Thompson M, Stevens R, et al. Normal ranges of heart rate and respiratory rate in children from birth to 18 years of age: a systematic review of observational studies. *Lancet*. 2011; 377:1011-1018. Available at: <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3789232/>

Hernandez-Madrid A, Paul T, Abrams D, et al. Arrhythmias in congenital heart disease: A position paper of the European Heart Rhythm Association (EHRA), Association for European Paediatric and Congenital Cardiology (AEPC), and the European Society of Cardiology (ESC) Working Group on Grown-up Congenital Heart Disease, endorsed by HRS, PACES, APHRS, and SOLAECE. *Europace*. 2018; 0:1-35. Available at: <https://academic.oup.com/europace/advance-article-abstract/doi/10.1093/europace/eux380/4944677>

January CT, Wann LS, Alpert JS, et al. 2014 AHA/ACC/HRS guideline for the management of patients with atrial fibrillation: A report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines and the Heart Rhythm Society. *J Am Coll Cardiol*. 2014; 64(21):e1-76.

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. *Heart Rhythm*. 2014; 11:e102-e165.

Kugler JD. Sinus node dysfunction. In: Pediatric Arrhythmias: Electrophysiology and Pacing, Gillette PC, Garson AG Jr (Eds), WB Saunders, Philadelphia 1990. p.250.

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. *J Am Coll Cardiol*. 2019; 74(7):e51-e156.

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*. 2017; 136(5):e60-e122.

Varosy PD, Chen LY, Miller AL, et al. 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*. 2017; 136(5):e123-e135.

**Reviewed / Approved by NIA Clinical Guideline Committee**

**Disclaimer:** Magellan Healthcare service authorization policies do not constitute medical advice and are not intended to govern or otherwise influence the practice of medicine. These policies are not meant to supplant your normal procedures, evaluation, diagnosis, treatment and/or care plans for your patients. Your professional judgement must be exercised and followed in all respects with regard to the treatment and care of your patients. These policies apply to all Magellan Healthcare subsidiaries including, but not limited to, National Imaging Associates (“Magellan”). The policies constitute only the reimbursement and coverage guidelines of Magellan. Coverage for services varies for individual members in accordance with the terms and conditions of applicable Certificates of Coverage, Summary Plan Descriptions, or contracts with governing regulatory agencies. Magellan reserves the right to review and update the guidelines at its sole discretion. Notice of such changes, if necessary, shall be provided in accordance with the terms and conditions of provider agreements and any applicable laws or regulations.