2016 Procedures Criteria

PATIENT:	Name	DOB	ID#	GROUP#
	Facility		Service Date	
PROVIDER:	Name		Fax#	Phone#
	Signature		Date	NPI/ID#

ICD-9:
ICD-10:
CPT®:

Subset: Pacemaker Insertion, Biventricular[1, 2, 3, 4, 5, 6]
Requested Service: Pacemaker Insertion, Biventricular
Age: Age ≥ 18

INSTRUCTIONS: Choose one of the following options and continue to the appropriate section

☐ 10. Ambulatory New York Heart Association Class IV heart failure (HF) by history or physical examination

☐ 20. New York Heart Association Class II heart failure (HF) by history or physical examination

☐ 30. New York Heart Association Class III heart failure (HF) by history or physical examination

☐ 10. Ambulatory New York Heart Association Class IV heart failure (HF) by history or physical examination

1. Choose one:

☐ A) QRS duration ≥ 120 and < 150 milliseconds by electrocardiogram (ECG)[7]

☐ B) QRS duration ≥ 150 milliseconds by electrocardiogram (ECG)

☐ C) Other clinical information (add comment)

- If option A selected, then go to question 2
- If option B selected, then go to question 4
- No other options lead to the requested service

2. Choose all that apply:

☐ A) Ejection fraction (EF) ≤ 35% by testing[8]

☐ B) Left bundle branch block (LBBB) by electrocardiogram (ECG)

☐ C) Continued symptoms or findings despite optimal medical treatment[9, 10]

☐ D) Life expectancy ≥ 1 year[11]

☐ E) Other clinical information (add comment)

- If the number of options selected is 4 and option E not selected, then go to question 3
- No other options lead to the requested service

3. Evaluation of atrial arrhythmia, Choose one:[12]

- ☐ A) No evidence of atrial arrhythmia
- ☐ B) Atrial arrhythmia treated with atrioventricular (AV) junction ablation
- ☐ C) Atrial arrhythmia treated with atrioventricular (AV) blocking medication
- ☐ D) Other clinical information (add comment)

- If option A, B or C selected, then the rule is satisfied; you may stop here ***(Inpatient)***
- No other options lead to the requested service

4. Choose all that apply:

- ☐ A) Ejection fraction (EF) ≤ 35% by testing[8]
- ☐ B) Continued symptoms or findings despite optimal medical treatment[9, 10]
- ☐ C) Life expectancy ≥ 1 year[11]
- ☐ D) Other clinical information (add comment)

- If the number of options selected is 3 and option D not selected, then go to question 3
- No other options lead to the requested service

☐ 20. New York Heart Association Class II heart failure (HF) by history or physical examination

1. Choose all that apply:

- ☐ A) Ejection fraction (EF) ≤ 35% by testing[8, 13]
- ☐ B) QRS duration ≥ 120 milliseconds by electrocardiogram (ECG)[7, 14]
- ☐ C) Left bundle branch block (LBBB) by electrocardiogram (ECG)
- ☐ D) Continued symptoms or findings despite optimal medical treatment[9, 10]
- ☐ E) Life expectancy ≥ 1 year[11]
- ☐ F) Other clinical information (add comment)

- If the number of options selected is 5 and option F not selected, then go to question 2
- No other options lead to the requested service

2. Evaluation of atrial arrhythmia, Choose one:[12]

- ☐ A) No evidence of atrial arrhythmia
- ☐ B) Atrial arrhythmia treated with atrioventricular (AV) junction ablation
- ☐ C) Atrial arrhythmia treated with atrioventricular (AV) blocking medication
- ☐ D) Other clinical information (add comment)

- If option A, B or C selected, then the rule is satisfied; you may stop here ***(Inpatient)***
- No other options lead to the requested service

☐ 30. New York Heart Association Class III heart failure (HF) by history or physical examination

1. Choose one:

☐ 30. New York Heart Association Class III heart failure (HF) by history or physical examination ***(Continued...)***

- ☐ A) QRS duration ≥ 120 and < 150 milliseconds by electrocardiogram (ECG)[7]
- ☐ B) QRS duration ≥ 150 milliseconds by electrocardiogram (ECG)
- ☐ C) Other clinical information (add comment)

- If option A selected, then go to question 2
- If option B selected, then go to question 4
- No other options lead to the requested service

2. Choose all that apply:

- ☐ A) Ejection fraction (EF) ≤ 35% by testing[8]
- ☐ B) Left bundle branch block (LBBB) by electrocardiogram (ECG)
- ☐ C) Continued symptoms or findings despite optimal medical treatment[9, 10]
- ☐ D) Life expectancy ≥ 1 year[11]
- ☐ E) Other clinical information (add comment)

- If the number of options selected is 4 and option E not selected, then go to question 3
- No other options lead to the requested service

3. Evaluation of atrial arrhythmia, Choose one:[12]

- ☐ A) No evidence of atrial arrhythmia
- ☐ B) Atrial arrhythmia treated with atrioventricular (AV) junction ablation
- ☐ C) Atrial arrhythmia treated with atrioventricular (AV) blocking medication
- ☐ D) Other clinical information (add comment)

- If option A, B or C selected, then the rule is satisfied; you may stop here ***(Inpatient)***
- No other options lead to the requested service

4. Choose all that apply:

- ☐ A) Ejection fraction (EF) ≤ 35% by testing[8]
- ☐ B) Continued symptoms or findings despite optimal medical treatment[9, 10]
- ☐ C) Life expectancy ≥ 1 year[11]
- ☐ D) Other clinical information (add comment)

- If the number of options selected is 3 and option D not selected, then go to question 3
- No other options lead to the requested service

Notes

(1)
I/O Setting: Inpatient

(2)
These criteria include the following procedures:
Cardiac Resynchronization Therapy (CRT)

(3)
These criteria cover biventricular pacemaker insertion only. When a combined biventricular pacemaker and implantable cardioverter defibrillator insertion is planned, see the "Biventricular Pacemaker Insertion + Implantable Cardioverter Defibrillator (ICD) Insertion" criteria subset.

(4)
Biventricular pacemaker insertion involves the placement of electrodes into both the right atrium and right ventricle, as well as a third transvenous lead into the external wall of the left ventricle. It is technically more demanding than the insertion of a conventional pacemaker and may require echocardiography or coronary venogram to determine proper placement of the electrodes. Meta-analysis of multiple trials has shown implant success rates of 93% with procedure complication and mortality rates of 4.3% and 0.3%, respectively (McAlister et al., JAMA 2007; 297(22): 2502-2514). Cardiac resynchronization therapy, in addition to optimal medical treatment or defibrillator insertion, significantly reduces mortality rates for patients with heart failure (Wells et al., CMAJ 2011, 183: 421-9).

(5)
Cardiac resynchronization therapy (CRT) with a biventricular pacemaker aims to improve the pumping efficiency of the heart by enabling synchronous ventricular contraction after the device senses atrial systole. Several trials have demonstrated the efficacy of CRT in improving functional status and quality of life, improving ejection fraction, and reducing overall mortality and hospitalizations for heart failure in patients with Class II, Class III, and Class IV New York Heart Association heart failure (Epstein et al., Circulation 2013, 127: e283-352; Linde et al., J Am Coll Cardiol 2008, 52: 1834-43; McAlister et al., JAMA 2007; 297(22): 2502-2514).

(6)
These criteria do not cover biventricular pacing or cardiac resynchronization therapy (CRT) in patients with asymptomatic or New York Heart Association (NYHA) Class I heart failure (HF). The Multicenter Automatic Defibrillator Implantation Trial with Cardiac Resynchronization Therapy (MADIT-CRT) failed to show a significant reduction in the primary end-points of death or HF events with combined CRT and implantable cardioverter defibrillator (ICD) therapy over ICD therapy alone in patients with NYHA Class I HF (Moss et al., N Engl J Med 2009; 361(14): 1329-1338). There was also a trend towards less clinical efficacy by CRT in NYHA Class I patients compared to NYHA Class II patients in the REsynchronization reVErses Remodeling in Systolic left vEntricular dysfunction (REVERSE) trial (Daubert et al., J Am Coll Cardiol 2009; 54(20): 1837-1846).
The number of NYHA Class I patients compared to NYHA Class II patients enrolled in CRT trials is significantly smaller and current guidelines do not recommend CRT for patients with NYHA Class I HF. A recent systematic review demonstrated a significant reduction in HF events and hospitalizations with the use of CRT in asymptomatic patients with NYHA Class I HF; however, the risks and benefits of device implantation in an asymptomatic patient need careful consideration (Epstein et al., Circulation 2013, 127: e283-352; Adabag et al., J Am Coll Cardiol 2011, 58: 935-41).

(7)
The Cardiac Resynchronization Therapy in Patients with Heart Failure and Narrow QRS (RethinQ) trial examined the performance of cardiac resynchronization (CRT) in patients with heart failure and a narrow QRS (< 120 milliseconds). Results failed to show a benefit of CRT in these patients and further randomized, prospective studies are needed (Beshai et al., N Engl J Med 2007; 357(24): 2461-2471).

(8)
Testing includes imaging by transthoracic echocardiogram, transesophageal echocardiogram, left ventriculogram, or radionuclide ventriculogram.

(9)
The Multicenter Insync Randomized Clinical Evaluation (MIRACLE), Multisite Stimulation in Cardiomyopathy (MUSTIC), Comparison of Medical Therapy, Pacing, and Defibrillation in Heart Failure (COMPANION), Multicenter Automatic Defibrillator Implantation Trial with Cardiac Resynchronization Therapy (MADIT-CRT), and the Cardiac Resynchronization-Heart Failure (CARE-HF) trials demonstrated the superiority of using cardiac resynchronization therapy (CRT) with optimal medical therapy over treatment of heart failure (HF) with medical therapy alone. These studies concluded that CRT with optimal medical therapy was associated with clinically significant symptom improvement, a 40% to 50% decrease in the frequency of hospitalization for HF events, and a relative risk reduction of 22% for overall mortality (Moss et al., N Engl J Med 2009; 361(14): 1329-1338; Cleland et al., N Engl J Med 2005; 352(15): 1539-1549; Bristow et al., N Engl J Med 2004; 350(21): 2140-2150; Young et al., JAMA 2003; 289(20): 2685-2694; Linde et al., J Am Coll Cardiol

2002; 40(1): 111-118).

(10)

Medical treatment in patients with heart failure (HF) should include beta blockers and angiotensin converting enzyme (ACE) inhibitors. Beta blockers (e.g., carvedilol) and ACE inhibitors have been shown to reduce mortality and morbidity. Patients who are intolerant of ACE inhibitors may benefit from angiotensin receptor blockers. Diuretics (e.g., furosemide) are recommended in patients with evidence of fluid retention. Aldosterone receptor antagonists (e.g., spironolactone) have been shown to reduce mortality and HF hospitalizations in patients with New York Heart Association Class II to IV HF and an ejection fraction of 35% or less; however, careful monitoring for hyperkalemia and renal insufficiency is required (Yancy et al., Circulation 2013, 128(16):e240-319).

(11)

Since the relevant studies used to support the use of pacemakers and defibrillators have typically excluded patients with cardiogenic shock, irreversible brain damage, or other comorbidities that would shorten their life expectancy (e.g., renal failure, liver failure, pulmonary hypertension, stroke), patients with a life expectancy of less than one year are not candidates for these devices (Epstein et al., Circulation 2013, 127: e283-352; Dickstein et al., Eur Heart J 2010, 31: 2677-87; Lindenfeld et al., J Card Fail 2010, 16: e1-194).

(12)

Atrial arrhythmias, including atrial fibrillation, atrial flutter, narrow complex tachycardia, and multifocal tachycardia, all result in irregular atrial contractions. Since a biventricular pacemaker senses a normal atrial contraction, these arrhythmias preclude insertion of this type of pacemaker unless the arrhythmia is treated with atrioventricular (AV) blocking medications or AV junction ablation.

(13)

Cardiac resynchronization therapy (CRT) is recommended for patients with New York Heart Association (NYHA) Class II heart failure (HF) and an ejection fraction (EF) ≤ 35% (Epstein et al., Circulation 2013, 127: e283-352; Dickstein et al., Eur Heart J 2010, 31: 2677-87). A recent post-hoc analysis of the Multicenter Automatic Defibrillator Implantation Trial with Cardiac Resynchronization Therapy (MADIT-CRT) demonstrated the benefit of CRT in patients with NYHA Class II HF regardless of EF. In addition, improved echocardiographic response was most significant in patients with EF >30% (median of 31.8%) (Kutyifa et al., J Am Coll Cardiol 2013, 61: 936-44).

(14)

Although sub-group analyses of the Multicenter Automatic Defibrillator Implantation Trial with Cardiac Resynchronization Therapy (MADIT-CRT), the REsynchronization reVErses Remodeling in Systolic left vEntricular dysfunction (REVERSE) trial, and the Resynchronization-Defibrillation for Ambulatory Heart Failure Trial (RAFT) found that patients with New York Heart Association (NYHA) Class II heart failure (HF), a QRS duration of ≥ 150 milliseconds, and a left bundle branch block derived the most benefit from cardiac resynchronization therapy (CRT), current guidelines indicate that CRT may be beneficial in patients with NYHA Class II HF and a QRS ≥ 120 milliseconds (Epstein et al., Circulation 2013, 127: e283-352; Dickstein et al., Eur Heart J 2010, 31: 2677-87; Solomon et al., Circulation 2010, 122: 985-92; Tang et al., N Engl J Med 2010, 363: 2385-95; Moss et al., N Engl J Med 2009; 361(14): 1329-1338).

Pacemaker Insertion, Biventricular

ICD-9 (circle all that apply): 00.50, 00.53, 37.74, 428.0, 428.1, 428.20, 428.21, 428.22, 428.23, 428.30, 428.31, 428.32, 428.33, 428.40, 428.41, 428.42, 428.43, 428.9, Other_____

ICD-10-CM (circle all that apply): I50.1, I50.20, I50.21, I50.22, I50.23, I50.2, I50.30, I50.31, I50.32, I50.33, I50.3, I50.40, I50.41, I50.42, I50.43, I50.4, I50.9, Other_____

ICD-10-PCS (circle all that apply): 02HN0JZ, 02HN0MZ, 02HN3JZ, 02HN3MZ, 0JH607Z, 0JH637Z, 0JH806Z, Other_____

CPT® (circle all that apply): 33202, 33203, 33224, 33225, Other_____