

2016 Procedures Criteria

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

ICD-9:
 ICD-10:
 CPT®:
 HCPCS:

Subset: Pacemaker Insertion, Biventricular + Implantable Cardioverter Defibrillator (ICD) Insertion^(1, 2, 3, 4, 5, 6)
Requested Service: Pacemaker Insertion, Biventricular + Implantable Cardioverter Defibrillator (ICD) Insertion
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 25
- 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

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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 go to question 4
- No other options lead to the requested service

4. Risk for sudden cardiac death, Choose one:⁽¹³⁾

- A) Ventricular arrhythmia
- B) Ischemic cardiomyopathy by testing^(14, 15, 16)
- C) Hypertrophic cardiomyopathy by testing^(17, 15, 18)
- D) Brugada syndrome by electrocardiogram (ECG)^(19, 20)
- E) Long QT syndrome by electrocardiogram (ECG)^(21, 22)
- F) Arrhythmogenic right ventricular dysplasia (ARVD) by testing⁽²³⁾
- G) Catecholaminergic polymorphic ventricular tachycardia (VT) by testing⁽²⁴⁾
- H) Other clinical information (add comment)

- If option A selected, then go to question 5
- If option B selected, then go to question 16
- If option C selected, then go to question 19
- If option D or E selected, then go to question 22
- If option F selected, then go to question 23
- If option G selected, then go to question 24
- No other options lead to the requested service

5. Choose one:

- A) Cardiac arrest survivor^(25, 26)
- B) Inducible ventricular fibrillation (VF) at electrophysiology (EP) testing⁽²⁷⁾
- C) Spontaneous sustained (> 30 seconds) ventricular tachycardia (VT) by electrocardiogram (ECG)^(28, 26)
- D) Inducible sustained (> 30 seconds) ventricular tachycardia (VT) at electrophysiology (EP) testing^(28, 29)
- E) Spontaneous nonsustained (\leq 30 seconds) ventricular tachycardia (VT) by electrocardiogram (ECG)⁽³⁰⁾
- F) Inducible nonsustained (\leq 30 seconds) ventricular tachycardia (VT) at electrophysiology (EP) testing⁽³⁰⁾
- G) Other clinical information (add comment)

- If option A selected, then go to question 6
- If option B, C or D selected, then go to question 12
- If option E or F selected, then go to question 15
- No other options lead to the requested service

6. Choose one:

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

- A) Arrhythmia occurring during myocardial infarction (MI) hospitalization (urgent)^(31, 32)
- B) Without concomitant acute myocardial infarction (MI)
- C) Other clinical information (add comment)

- If option A selected, then go to question 7
- If option B selected, then go to question 10
- No other options lead to the requested service

7. Arrhythmia occurred > 48 hours post myocardial infarction (MI)

- Yes
- No

- If option Yes selected, then go to question 8
- No other options lead to the requested service

8. Coronary artery disease (CAD) evaluation by testing, Choose one:⁽³³⁾

- A) No coronary artery disease (CAD) or ischemia⁽³⁴⁾
- B) Stenosis not significant enough to warrant revascularization⁽³⁵⁾
- C) Percutaneous coronary intervention (PCI) or coronary artery bypass graft (CABG) performed⁽³⁶⁾
- D) Lesion not amenable to revascularization⁽³⁷⁾
- E) Other clinical information (add comment)

- If option A, B or D selected, then go to question 9
- No other options lead to the requested service

9. Transient or reversible causes excluded⁽³⁸⁾

- Yes
- No

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

10. Coronary artery disease (CAD) evaluation by testing, Choose one:⁽³³⁾

- A) No coronary artery disease (CAD) or ischemia⁽³⁴⁾
- B) Stenosis not significant enough to warrant revascularization⁽³⁵⁾
- C) Percutaneous coronary intervention (PCI) or coronary artery bypass graft (CABG) performed \geq 12 weeks prior^(36, 39)
- D) Lesion not amenable to revascularization⁽³⁷⁾
- E) Other clinical information (add comment)

- If option A, B, C or D selected, then go to question 11
- No other options lead to the requested service

11. Choose one:⁽⁴⁰⁾

- A) Continued arrhythmia after medical therapy or ablation
- B) Arrhythmia not amenable to medical therapy or ablation
- C) Other clinical information (add comment)

- If option A or B selected, then go to question 9
- No other options lead to the requested service

12. Choose one:

- A) Syncope by history⁽⁴¹⁾
- B) Structural heart disease (SHD) by transthoracic echocardiogram (TTE) or transesophageal echocardiogram (TEE)
- C) Other clinical information (add comment)

- If option A selected, then go to question 10
- If option B selected, then go to question 13
- No other options lead to the requested service

13. Choose all that apply:

- A) Left ventricular hypertrophy (LVH)
- B) Right ventricular hypertrophy (RVH)
- C) Ejection fraction (EF) \leq 40%⁽⁸⁾
- D) Mitral regurgitation (MR)
- E) Aortic regurgitation (AR)
- F) Mitral stenosis (MS)
- G) Aortic stenosis (AS)^(42, 43)
- H) Congenital heart disease⁽⁴⁴⁾
- I) Other clinical information (add comment)

- If 1 or more options A, B, C, D, E, F, G or H selected and option I not selected, then go to question 14
- No other options lead to the requested service

14. Coronary artery disease (CAD) evaluation by testing, Choose one:⁽³³⁾

- A) No coronary artery disease (CAD) or ischemia⁽³⁴⁾
- B) Stenosis not significant enough to warrant revascularization⁽³⁵⁾
- C) Percutaneous coronary intervention (PCI) or coronary artery bypass graft (CABG) performed \geq 12 weeks prior^(36, 39)
- D) Lesion not amenable to revascularization⁽³⁷⁾
- E) Other clinical information (add comment)

- If option A, B, C or D selected, then go to question 9
- No other options lead to the requested service

15. Choose all that apply:

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

- A) Myocardial infarction (MI) \geq 40 days prior^(45, 46)
- B) Inducible ventricular fibrillation (VF) or inducible sustained (> 30 seconds) ventricular tachycardia (VT) at electrophysiology (EP) testing^(28, 47)
- C) Other clinical information (add comment)

- If the number of options selected is 2 and option C not selected, then go to question 14
- No other options lead to the requested service

16. Myocardial infarction (MI) \geq 40 days prior^(48, 45)

- Yes
- No

- If option Yes selected, then go to question 17
- No other options lead to the requested service

17. Coronary artery disease (CAD) evaluation by testing, Choose one:⁽³³⁾

- A) No coronary artery disease (CAD) or ischemia⁽³⁴⁾
- B) Stenosis not significant enough to warrant revascularization⁽³⁵⁾
- C) Percutaneous coronary intervention (PCI) or coronary artery bypass graft (CABG) performed \geq 12 weeks prior^(36, 39)
- D) Lesion not amenable to revascularization⁽³⁷⁾
- E) Other clinical information (add comment)

- If option A, B, C or D selected, then go to question 18
- No other options lead to the requested service

18. Continued symptoms or findings despite optimal medical treatment⁽⁴⁹⁾

- Yes
- No

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

19. Risk factor for sudden cardiac death, Choose one:⁽⁵⁰⁾

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

- A) Cardiac arrest survivor
- B) Inducible ventricular fibrillation (VF) at electrophysiology (EP) testing
- C) Spontaneous sustained (> 30 seconds) ventricular tachycardia (VT) by electrocardiogram (ECG)⁽²⁸⁾
- D) Spontaneous nonsustained (\leq 30 seconds) ventricular tachycardia (VT) by electrocardiogram (ECG)⁽³⁰⁾
- E) Sudden cardiac death in a first degree relative \leq 40⁽⁵¹⁾
- F) Sudden cardiac death in a first degree relative with hypertrophic cardiomyopathy⁽⁵¹⁾
- G) Presyncope or syncope by history^(52, 53)
- H) Left ventricular or septal thickness \geq 30 mm by transthoracic echocardiogram (TTE) or transesophageal echocardiogram (TEE)
- I) Other clinical information (add comment)

- If option E, F, G or H selected, then the rule is satisfied; you may stop here (**Inpatient**)
- If option A, B, C or D selected, then go to question 20
- No other options lead to the requested service

20. Coronary artery disease (CAD) evaluation by testing, Choose one:⁽³³⁾

- A) No coronary artery disease (CAD) or ischemia⁽³⁴⁾
- B) Stenosis not significant enough to warrant revascularization⁽³⁵⁾
- C) Percutaneous coronary intervention (PCI) or coronary artery bypass graft (CABG) performed \geq 12 weeks prior^(36, 39)
- D) Lesion not amenable to revascularization⁽³⁷⁾
- E) Other clinical information (add comment)

- If option A, B, C or D selected, then go to question 21
- No other options lead to the requested service

21. Transient or reversible causes excluded⁽³⁸⁾

- Yes
- No

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

22. Choose one:

- A) Syncope by history⁽⁴¹⁾
- B) Ventricular tachycardia (VT) or ventricular fibrillation (VF) by electrocardiogram (ECG)
- C) Cardiac arrest survivor
- D) Other clinical information (add comment)

- If option A selected, then the rule is satisfied; you may stop here (**Inpatient**)
- If option B or C selected, then go to question 20
- No other options lead to the requested service

23. Risk factor for sudden cardiac death, Choose one:

- A) Cardiac arrest survivor
- B) Inducible ventricular fibrillation (VF) at electrophysiology (EP) testing
- C) Spontaneous sustained (> 30 seconds) ventricular tachycardia (VT) by electrocardiogram (ECG)⁽²⁸⁾
- D) Sudden cardiac death in a first degree relative with arrhythmogenic right ventricular dysplasia (ARVD)⁽⁵¹⁾
- E) Syncope by history⁽⁴¹⁾
- F) Dysplasia extending to the left ventricle⁽⁵⁴⁾
- G) Other clinical information (add comment)

- If option D, E or F selected, then the rule is satisfied; you may stop here (**Inpatient**)
- If option A, B or C selected, then go to question 20
- No other options lead to the requested service

24. Choose one:

- A) Syncope by history⁽⁴¹⁾
- B) Cardiac arrest survivor
- C) Other clinical information (add comment)

- If option A selected, then the rule is satisfied; you may stop here (**Inpatient**)
- If option B selected, then go to question 20
- No other options lead to the requested service

25. Choose all that apply:

- A) Ejection fraction (EF) \leq 35% by testing⁽⁸⁾
- B) Continued symptoms or findings despite optimal medical treatment^(9, 10)
- C) Life expectancy \geq 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) \leq 35% by testing^(8, 55)
- B) QRS duration \geq 120 milliseconds by electrocardiogram (ECG)^(7, 56)
- C) Left bundle branch block (LBBB) by electrocardiogram (ECG)
- D) Continued symptoms or findings despite optimal medical treatment^(9, 10)
- E) Life expectancy \geq 1 year⁽¹¹⁾
- F) Other clinical information (add comment)

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

- 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 go to question 3
- No other options lead to the requested service

3. Risk for sudden cardiac death, Choose one:⁽¹³⁾

- A) Ventricular arrhythmia
- B) Ischemic cardiomyopathy by testing^(14, 15, 16)
- C) Nonischemic dilated cardiomyopathy by testing^(15, 57, 58)
- D) Hypertrophic cardiomyopathy by testing^(17, 15, 18)
- E) Brugada syndrome by electrocardiogram (ECG)^(19, 20)
- F) Long QT syndrome by electrocardiogram (ECG)⁽²¹⁾
- G) Arrhythmogenic right ventricular dysplasia (ARVD) by testing⁽²³⁾
- H) Catecholaminergic polymorphic ventricular tachycardia (VT) by testing⁽²⁴⁾
- I) Other clinical information (add comment)

- If option A selected, then go to question 4
- If option B selected, then go to question 15
- If option C selected, then go to question 18
- If option D selected, then go to question 19
- If option E or F selected, then go to question 22
- If option G selected, then go to question 23
- If option H selected, then go to question 24
- No other options lead to the requested service

4. Choose one:

- A) Cardiac arrest survivor^(25, 26)
- B) Inducible ventricular fibrillation (VF) at electrophysiology (EP) testing⁽²⁷⁾
- C) Spontaneous sustained (> 30 seconds) ventricular tachycardia (VT) by electrocardiogram (ECG)^(28, 26)
- D) Inducible sustained (> 30 seconds) ventricular tachycardia (VT) at electrophysiology (EP) testing^(28, 29)
- E) Spontaneous nonsustained (\leq 30 seconds) ventricular tachycardia (VT) by electrocardiogram (ECG)⁽³⁰⁾
- F) Inducible nonsustained (\leq 30 seconds) ventricular tachycardia (VT) at electrophysiology (EP) testing⁽³⁰⁾
- G) Other clinical information (add comment)

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

- If option A selected, then go to question 5
- If option B, C or D selected, then go to question 11
- If option E or F selected, then go to question 14
- No other options lead to the requested service

5. Choose one:

- A) Arrhythmia occurring during myocardial infarction (MI) hospitalization (urgent)^(31, 32)
- B) Without concomitant acute myocardial infarction (MI)
- C) Other clinical information (add comment)

- If option A selected, then go to question 6
- If option B selected, then go to question 9
- No other options lead to the requested service

6. Arrhythmia occurred > 48 hours post myocardial infarction (MI)

- Yes
- No

- If option Yes selected, then go to question 7
- No other options lead to the requested service

7. Coronary artery disease (CAD) evaluation by testing, Choose one:⁽³³⁾

- A) No coronary artery disease (CAD) or ischemia⁽³⁴⁾
- B) Stenosis not significant enough to warrant revascularization⁽³⁵⁾
- C) Percutaneous coronary intervention (PCI) or coronary artery bypass graft (CABG) performed⁽³⁶⁾
- D) Lesion not amenable to revascularization⁽³⁷⁾
- E) Other clinical information (add comment)

- If option A, B or D selected, then go to question 8
- No other options lead to the requested service

8. Transient or reversible causes excluded⁽³⁸⁾

- Yes
- No

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

9. Coronary artery disease (CAD) evaluation by testing, Choose one:⁽³³⁾

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

- A) No coronary artery disease (CAD) or ischemia⁽³⁴⁾
- B) Stenosis not significant enough to warrant revascularization⁽³⁵⁾
- C) Percutaneous coronary intervention (PCI) or coronary artery bypass graft (CABG) performed \geq 12 weeks prior^(36, 39)
- D) Lesion not amenable to revascularization⁽³⁷⁾
- E) Other clinical information (add comment)

- If option A, B, C or D selected, then go to question 10
- No other options lead to the requested service

10. Choose one:⁽⁴⁰⁾

- A) Continued arrhythmia after medical therapy or ablation
- B) Arrhythmia not amenable to medical therapy or ablation
- C) Other clinical information (add comment)

- If option A or B selected, then go to question 8
- No other options lead to the requested service

11. Choose one:

- A) Syncope by history⁽⁴¹⁾
- B) Structural heart disease (SHD) by transthoracic echocardiogram (TTE) or transesophageal echocardiogram (TEE)
- C) Other clinical information (add comment)

- If option A selected, then go to question 9
- If option B selected, then go to question 12
- No other options lead to the requested service

12. Choose all that apply:

- A) Left ventricular hypertrophy (LVH)
- B) Right ventricular hypertrophy (RVH)
- C) Ejection fraction (EF) \leq 40%⁽⁸⁾
- D) Mitral regurgitation (MR)
- E) Aortic regurgitation (AR)
- F) Mitral stenosis (MS)
- G) Aortic stenosis (AS)^(42, 43)
- H) Congenital heart disease⁽⁴⁴⁾
- I) Other clinical information (add comment)

- If 1 or more options A, B, C, D, E, F, G or H selected and option I not selected, then go to question 13
- No other options lead to the requested service

13. Coronary artery disease (CAD) evaluation by testing, Choose one:⁽³³⁾

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

- A) No coronary artery disease (CAD) or ischemia⁽³⁴⁾
- B) Stenosis not significant enough to warrant revascularization⁽³⁵⁾
- C) Percutaneous coronary intervention (PCI) or coronary artery bypass graft (CABG) performed \geq 12 weeks prior^(36, 39)
- D) Lesion not amenable to revascularization⁽³⁷⁾
- E) Other clinical information (add comment)

- If option A, B, C or D selected, then go to question 8
- No other options lead to the requested service

14. Choose all that apply:

- A) Myocardial infarction (MI) \geq 40 days prior^(45, 46)
- B) Inducible ventricular fibrillation (VF) or inducible sustained ($>$ 30 seconds) ventricular tachycardia (VT) at electrophysiology (EP) testing^(28, 47)
- C) Other clinical information (add comment)

- If the number of options selected is 2 and option C not selected, then go to question 13
- No other options lead to the requested service

15. Myocardial infarction (MI) \geq 40 days prior^(48, 45)

- Yes
- No

- If option Yes selected, then go to question 16
- No other options lead to the requested service

16. Coronary artery disease (CAD) evaluation by testing, Choose one:⁽³³⁾

- A) No coronary artery disease (CAD) or ischemia⁽³⁴⁾
- B) Stenosis not significant enough to warrant revascularization⁽³⁵⁾
- C) Percutaneous coronary intervention (PCI) or coronary artery bypass graft (CABG) performed \geq 12 weeks prior^(36, 39)
- D) Lesion not amenable to revascularization⁽³⁷⁾
- E) Other clinical information (add comment)

- If option A, B, C or D selected, then go to question 17
- No other options lead to the requested service

17. Continued symptoms or findings despite optimal medical treatment⁽⁴⁹⁾

- Yes
- No

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

18. Continued symptoms or findings despite optimal medical treatment^(49, 59)

- Yes
 No

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

19. Risk factor for sudden cardiac death, Choose one:⁽⁵⁰⁾

- A) Cardiac arrest survivor
- B) Inducible ventricular fibrillation (VF) at electrophysiology (EP) testing
- C) Spontaneous sustained (> 30 seconds) ventricular tachycardia (VT) by electrocardiogram (ECG)⁽²⁸⁾
- D) Spontaneous nonsustained (\leq 30 seconds) ventricular tachycardia (VT) by electrocardiogram (ECG)⁽³⁰⁾
- E) Sudden cardiac death in a first degree relative \leq 40⁽⁵¹⁾
- F) Sudden cardiac death in a first degree relative with hypertrophic cardiomyopathy⁽⁵¹⁾
- G) Presyncope or syncope by history^(52, 53)
- H) Left ventricular or septal thickness \geq 30 mm by transthoracic echocardiogram (TTE) or transesophageal echocardiogram (TEE)
- I) Other clinical information (add comment)

- If option E, F, G or H selected, then the rule is satisfied; you may stop here (**Inpatient**)
- If option A, B, C or D selected, then go to question 20
- No other options lead to the requested service

20. Coronary artery disease (CAD) evaluation by testing, Choose one:⁽³³⁾

- A) No coronary artery disease (CAD) or ischemia⁽³⁴⁾
- B) Stenosis not significant enough to warrant revascularization⁽³⁵⁾
- C) Percutaneous coronary intervention (PCI) or coronary artery bypass graft (CABG) performed \geq 12 weeks prior^(36, 39)
- D) Lesion not amenable to revascularization⁽³⁷⁾
- E) Other clinical information (add comment)

- If option A, B, C or D selected, then go to question 21
- No other options lead to the requested service

21. Transient or reversible causes excluded⁽³⁸⁾

- Yes
 No

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

22. Choose one:

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

- A) Syncope by history⁽⁴¹⁾
- B) Ventricular tachycardia (VT) or ventricular fibrillation (VF) by electrocardiogram (ECG)
- C) Cardiac arrest survivor
- D) Other clinical information (add comment)

- If option A selected, then the rule is satisfied; you may stop here (*Inpatient*)
- If option B or C selected, then go to question 20
- No other options lead to the requested service

23. Risk factor for sudden cardiac death, Choose one:

- A) Cardiac arrest survivor
- B) Inducible ventricular fibrillation (VF) at electrophysiology (EP) testing
- C) Spontaneous sustained (> 30 seconds) ventricular tachycardia (VT) by electrocardiogram (ECG)⁽²⁸⁾
- D) Sudden cardiac death in a first degree relative with arrhythmogenic right ventricular dysplasia (ARVD)⁽⁵¹⁾
- E) Syncope by history⁽⁴¹⁾
- F) Dysplasia extending to the left ventricle⁽⁵⁴⁾
- G) Other clinical information (add comment)

- If option D, E or F selected, then the rule is satisfied; you may stop here (*Inpatient*)
- If option A, B or C selected, then go to question 20
- No other options lead to the requested service

24. Choose one:

- A) Syncope by history⁽⁴¹⁾
- B) Cardiac arrest survivor
- C) Other clinical information (add comment)

- If option A selected, then the rule is satisfied; you may stop here (*Inpatient*)
- If option B selected, then go to question 20
- 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:

- 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 26
- No other options lead to the requested service

2. Choose all that apply:

- A) Ejection fraction (EF) \leq 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 \geq 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 go to question 4
- No other options lead to the requested service

4. Risk for sudden cardiac death, Choose one:⁽¹³⁾

- A) Ventricular arrhythmia
- B) Ischemic cardiomyopathy by testing^(14, 15, 16)
- C) Nonischemic dilated cardiomyopathy by testing^(15, 57, 58)
- D) Hypertrophic cardiomyopathy by testing^(17, 15, 18)
- E) Brugada syndrome by electrocardiogram (ECG)^(19, 20)
- F) Long QT syndrome by electrocardiogram (ECG)⁽²¹⁾
- G) Arrhythmogenic right ventricular dysplasia (ARVD) by testing⁽²³⁾
- H) Catecholaminergic polymorphic ventricular tachycardia (VT) by testing⁽²⁴⁾
- I) Other clinical information (add comment)

- If option A selected, then go to question 5
- If option B selected, then go to question 16
- If option C selected, then go to question 19
- If option D selected, then go to question 20
- If option E or F selected, then go to question 23
- If option G selected, then go to question 24
- If option H selected, then go to question 25
- No other options lead to the requested service

5. Choose one:

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

- A) Cardiac arrest survivor^(25, 26)
- B) Inducible ventricular fibrillation (VF) at electrophysiology (EP) testing⁽²⁷⁾
- C) Spontaneous sustained (> 30 seconds) ventricular tachycardia (VT) by electrocardiogram (ECG)^(28, 26)
- D) Inducible sustained (> 30 seconds) ventricular tachycardia (VT) at electrophysiology (EP) testing^(28, 29)
- E) Spontaneous nonsustained (\leq 30 seconds) ventricular tachycardia (VT) by electrocardiogram (ECG)⁽³⁰⁾
- F) Inducible nonsustained (\leq 30 seconds) ventricular tachycardia (VT) at electrophysiology (EP) testing⁽³⁰⁾
- G) Other clinical information (add comment)

- If option A selected, then go to question 6
- If option B, C or D selected, then go to question 12
- If option E or F selected, then go to question 15
- No other options lead to the requested service

6. Choose one:

- A) Arrhythmia occurring during myocardial infarction (MI) hospitalization (urgent)^(31, 32)
- B) Without concomitant acute myocardial infarction (MI)
- C) Other clinical information (add comment)

- If option A selected, then go to question 7
- If option B selected, then go to question 10
- No other options lead to the requested service

7. Arrhythmia occurred > 48 hours post myocardial infarction (MI)

- Yes
- No

- If option Yes selected, then go to question 8
- No other options lead to the requested service

8. Coronary artery disease (CAD) evaluation by testing, Choose one:⁽³³⁾

- A) No coronary artery disease (CAD) or ischemia⁽³⁴⁾
- B) Stenosis not significant enough to warrant revascularization⁽³⁵⁾
- C) Percutaneous coronary intervention (PCI) or coronary artery bypass graft (CABG) performed⁽³⁶⁾
- D) Lesion not amenable to revascularization⁽³⁷⁾
- E) Other clinical information (add comment)

- If option A, B or D selected, then go to question 9
- No other options lead to the requested service

9. Transient or reversible causes excluded⁽³⁸⁾

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

Yes

No

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

10. Coronary artery disease (CAD) evaluation by testing, Choose one:⁽³³⁾

A) No coronary artery disease (CAD) or ischemia⁽³⁴⁾

B) Stenosis not significant enough to warrant revascularization⁽³⁵⁾

C) Percutaneous coronary intervention (PCI) or coronary artery bypass graft (CABG) performed \geq 12 weeks prior^(36, 39)

D) Lesion not amenable to revascularization⁽³⁷⁾

E) Other clinical information (add comment)

- If option A, B, C or D selected, then go to question 11
- No other options lead to the requested service

11. Choose one:⁽⁴⁰⁾

A) Continued arrhythmia after medical therapy or ablation

B) Arrhythmia not amenable to medical therapy or ablation

C) Other clinical information (add comment)

- If option A or B selected, then go to question 9
- No other options lead to the requested service

12. Choose one:

A) Syncope by history⁽⁴¹⁾

B) Structural heart disease (SHD) by transthoracic echocardiogram (TTE) or transesophageal echocardiogram (TEE)

C) Other clinical information (add comment)

- If option A selected, then go to question 10
- If option B selected, then go to question 13
- No other options lead to the requested service

13. Choose all that apply:

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

- A) Left ventricular hypertrophy (LVH)
- B) Right ventricular hypertrophy (RVH)
- C) Ejection fraction (EF) \leq 40%⁽⁸⁾
- D) Mitral regurgitation (MR)
- E) Aortic regurgitation (AR)
- F) Mitral stenosis (MS)
- G) Aortic stenosis (AS)^(42, 43)
- H) Congenital heart disease⁽⁴⁴⁾
- I) Other clinical information (add comment)

- If 1 or more options A, B, C, D, E, F, G or H selected and option I not selected, then go to question 14
- No other options lead to the requested service

14. Coronary artery disease (CAD) evaluation by testing, Choose one:⁽³³⁾

- A) No coronary artery disease (CAD) or ischemia⁽³⁴⁾
- B) Stenosis not significant enough to warrant revascularization⁽³⁵⁾
- C) Percutaneous coronary intervention (PCI) or coronary artery bypass graft (CABG) performed \geq 12 weeks prior^(36, 39)
- D) Lesion not amenable to revascularization⁽³⁷⁾
- E) Other clinical information (add comment)

- If option A, B, C or D selected, then go to question 9
- No other options lead to the requested service

15. Choose all that apply:

- A) Myocardial infarction (MI) \geq 40 days prior^(45, 46)
- B) Inducible ventricular fibrillation (VF) or inducible sustained (> 30 seconds) ventricular tachycardia (VT) at electrophysiology (EP) testing^(28, 47)
- C) Other clinical information (add comment)

- If the number of options selected is 2 and option C not selected, then go to question 14
- No other options lead to the requested service

16. Myocardial infarction (MI) \geq 40 days prior^(48, 45)

- Yes
- No

- If option Yes selected, then go to question 17
- No other options lead to the requested service

17. Coronary artery disease (CAD) evaluation by testing, Choose one:⁽³³⁾

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

- A) No coronary artery disease (CAD) or ischemia⁽³⁴⁾
- B) Stenosis not significant enough to warrant revascularization⁽³⁵⁾
- C) Percutaneous coronary intervention (PCI) or coronary artery bypass graft (CABG) performed \geq 12 weeks prior^(36, 39)
- D) Lesion not amenable to revascularization⁽³⁷⁾
- E) Other clinical information (add comment)

- If option A, B, C or D selected, then go to question 18
- No other options lead to the requested service

18. Continued symptoms or findings despite optimal medical treatment⁽⁴⁹⁾

- Yes
- No

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

19. Continued symptoms or findings despite optimal medical treatment^(49, 59)

- Yes
- No

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

20. Risk factor for sudden cardiac death, Choose one:⁽⁵⁰⁾

- A) Cardiac arrest survivor
- B) Inducible ventricular fibrillation (VF) at electrophysiology (EP) testing
- C) Spontaneous sustained (> 30 seconds) ventricular tachycardia (VT) by electrocardiogram (ECG)⁽²⁸⁾
- D) Spontaneous nonsustained (\leq 30 seconds) ventricular tachycardia (VT) by electrocardiogram (ECG)⁽³⁰⁾
- E) Sudden cardiac death in a first degree relative \leq 40⁽⁵¹⁾
- F) Sudden cardiac death in a first degree relative with hypertrophic cardiomyopathy⁽⁵¹⁾
- G) Presyncope or syncope by history^(52, 53)
- H) Left ventricular or septal thickness \geq 30 mm by transthoracic echocardiogram (TTE) or transesophageal echocardiogram (TEE)
- I) Other clinical information (add comment)

- If option E, F, G or H selected, then the rule is satisfied; you may stop here (**Inpatient**)
- If option A, B, C or D selected, then go to question 21
- No other options lead to the requested service

21. Coronary artery disease (CAD) evaluation by testing, Choose one:⁽³³⁾

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

- A) No coronary artery disease (CAD) or ischemia⁽³⁴⁾
- B) Stenosis not significant enough to warrant revascularization⁽³⁵⁾
- C) Percutaneous coronary intervention (PCI) or coronary artery bypass graft (CABG) performed \geq 12 weeks prior^(36, 39)
- D) Lesion not amenable to revascularization⁽³⁷⁾
- E) Other clinical information (add comment)

- If option A, B, C or D selected, then go to question 22
- No other options lead to the requested service

22. Transient or reversible causes excluded⁽³⁸⁾

- Yes
- No

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

23. Choose one:

- A) Syncope by history⁽⁴¹⁾
- B) Ventricular tachycardia (VT) or ventricular fibrillation (VF) by electrocardiogram (ECG)
- C) Cardiac arrest survivor
- D) Other clinical information (add comment)

- If option A selected, then the rule is satisfied; you may stop here (**Inpatient**)
- If option B or C selected, then go to question 21
- No other options lead to the requested service

24. Risk factor for sudden cardiac death, Choose one:

- A) Cardiac arrest survivor
- B) Inducible ventricular fibrillation (VF) at electrophysiology (EP) testing
- C) Spontaneous sustained (> 30 seconds) ventricular tachycardia (VT) by electrocardiogram (ECG)⁽²⁸⁾
- D) Sudden cardiac death in a first degree relative with arrhythmogenic right ventricular dysplasia (ARVD)⁽⁵¹⁾
- E) Syncope by history⁽⁴¹⁾
- F) Dysplasia extending to the left ventricle⁽⁵⁴⁾
- G) Other clinical information (add comment)

- If option D, E or F selected, then the rule is satisfied; you may stop here (**Inpatient**)
- If option A, B or C selected, then go to question 21
- No other options lead to the requested service

25. Choose one:

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

- A) Syncope by history⁽⁴¹⁾
- B) Cardiac arrest survivor
- C) Other clinical information (add comment)

- If option A selected, then the rule is satisfied; you may stop here (**Inpatient**)
- If option B selected, then go to question 21
- No other options lead to the requested service

26. Choose all that apply:

- A) Ejection fraction (EF) \leq 35% by testing⁽⁸⁾
- B) Continued symptoms or findings despite optimal medical treatment^(9, 10)
- C) Life expectancy \geq 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-Implantable Cardioverter Defibrillator (CRT-ICD) Insertion

Cardiac Resynchronization Therapy-Defibrillator (CRT-D) Insertion

(3)

These criteria cover biventricular pacemaker insertion with an implantable cardioverter defibrillator (ICD). Criteria must be met for both the pacemaker and ICD.

(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)

Patients with heart failure (HF) treated with optimal medical treatment and combined cardiac resynchronization therapy (CRT) and implanted cardioverter defibrillator (ICD) have improved quality of life, functional status, and exercise capacity when compared to controls (Veazie et al., *J Am Coll Cardiol* 2012, 60: 1940-4; McAlister et al., *JAMA* 2007; 297(22): 2502-2514). Randomized controlled trials of patients with HF and cardiac dyssynchrony have shown a 34% to 40% decrease in the risk of death or HF events when CRT was combined with ICD therapy (Moss et al., *N Engl J Med* 2009; 361(14): 1329-1338; Bristow et al., *N Engl J Med* 2004; 350(21): 2140-2150).

Placement of an ICD at the time of CRT is only appropriate if the indications for ICD are met (Stabile et al., *Future Cardiol* 2009; 5(6): 567-572).

(14)

Def: Ischemic cardiomyopathy is the weakening of heart muscle due to prior myocardial infarction or due to chronic blockages of the coronary arteries.

(15)

Testing may be by angiogram, transthoracic echocardiogram (TTE), transesophageal echocardiogram (TEE), or cardiac MRI.

(16)

The Sudden Cardiac Death in Heart Failure Trial (SCD-HeFT) found that a simple shock-only implantable cardioverter defibrillator significantly reduced the overall risk of death by 23% in patients with an ejection fraction of 35% or less due to ischemic or nonischemic cardiomyopathy (Bardy et al., *N Engl J Med* 2005; 352(3): 225-237). A recent meta-analysis supported the results of this study (Theuns et al., *Europace* 2010, 12: 1564-70).

(17)

Def: Hypertrophic cardiomyopathy is a disease process characterized by abnormal thickening of the heart muscle.

(18)

Although sudden cardiac death related to hypertrophic cardiomyopathy occurs most commonly during mild exertion, sedentary activities, or during sleep, it can also be triggered by vigorous physical exertion. Hypertrophic cardiomyopathy is the most common cause of cardiovascular-related sudden cardiac death in young people, including competitive athletes (Epstein et al., *Circulation* 2013, 127: e283-352; Zipes et al., *Circulation* 2006; 114(10): e385-484).

(19)

Brugada syndrome is characterized by ST-segment elevation in the right precordial leads (type 1 ECG) and a propensity for ventricular arrhythmias and sudden cardiac death in patients with structurally normal hearts. It is the cause of 4% to 12% of all sudden cardiac deaths and up to 20% of sudden cardiac deaths that occur in the normal heart. Although most patients with Brugada syndrome remain asymptomatic, the most common presenting symptoms are syncope and sudden cardiac arrest (Berne and Brugada, *Circ J* 2012, 76: 1563-71; Antzelevitch et al., *Heart Rhythm* 2005, 2: 429-40).

(20)

Inducibility of ventricular arrhythmias at electrophysiology (EP) testing in asymptomatic patients with Brugada syndrome may be an important tool in identifying patients at high risk for sudden cardiac death (Antzelevitch et al., *Heart Rhythm* 2005, 2: 429-40; Brugada et al., *Circulation* 2002, 105: 73-8). Despite this, the use of EP testing to stratify risk has remained controversial. Recent studies remain unable to confirm a definitive relationship between positive EP studies and future arrhythmic events in asymptomatic patients (Piori et al., *J Am Coll Cardiol* 2012, 59: 37-45; Probst et al., *Circulation* 2010; 121(5): 635-643).

(21)

Def: Congenital long QT syndrome is an inherited disorder in which delayed ventricular repolarization increases the risk for ventricular arrhythmias and sudden cardiac death.

(22)

Medical therapy with beta blockers is considered to be first-line prophylactic therapy and is associated with a significant and pronounced reduction in the risk of life-threatening ventricular arrhythmias in high risk patients. Patients who remain symptomatic despite beta blocker therapy should be considered for more invasive therapies including implantable cardioverter defibrillator placement (Epstein et al., *Circulation* 2013, 127: e283-352; Zipes et al., *Circulation* 2006; 114(10): e385-484).

(23)

Arrhythmogenic right ventricular dysplasia, also known as arrhythmogenic right ventricular cardiomyopathy, is a genetically determined heart muscle disorder that leads to fibro-fatty replacement of the myocardium in the right ventricle. Pathology may extend to the left ventricle as well. Patients typically present with syncope or heart failure. The resulting structural abnormalities can lead to ventricular arrhythmias including ventricular tachycardia and, in some cases, sudden death. Evaluation of this disorder is challenging and a number of studies (e.g., electrocardiogram, transthoracic echocardiogram, MRI, CT, biopsy) are usually required to assess for ventricular abnormalities and confirm the diagnosis (Calkins, *Curr Probl Cardiol* 2013, 38: 103-23).

(24)

Catecholaminergic polymorphic ventricular tachycardia (VT) is a rhythm disorder of the ventricles that occurs in genetically predisposed individuals. It is characterized by episodes of VT and syncope resulting from physical or emotional stress. A resting electrocardiogram is typically normal and, therefore, exercise stress testing is essential in establishing a diagnosis. Genetic testing can also identify those with the disorder (Napolitano et al., *Circulation* 2012, 125: 2027-34; Obeyesekere et al., *Circ Arrhythm Electrophysiol* 2011, 4: 958-64).

(25)

Sudden cardiac death can be attributable to a number of causes. Studies suggest that the majority of cases of sudden cardiac death result from ventricular fibrillation, while a small number of cases can be attributed to bradyarrhythmias. The primary cause of sudden cardiac death is coronary artery disease followed by cardiomyopathy. Other causes include congenital anomalies (e.g., tetralogy of Fallot, transposition of the great vessels), coronary artery anomalies, channelopathies (e.g., long QT syndrome, Brugada syndrome), and other vague causes (e.g., illicit and prescription drugs, blunt trauma to the chest) (Zipes et al., *Circulation* 2006; 114(10): e385-484).

(26)

Several studies, including the Antiarrhythmics Versus Implantable Defibrillators (AVID) study, Cardiac Arrest Study Hamburg (CASH), Canadian Implantable Defibrillator Study (CIDS), and the Sudden Cardiac Death in Heart Failure Trial (SCD-HeFT) showed the effectiveness of implantable cardioverter defibrillators (ICDs) in cardiac arrest survivors or after sustained ventricular tachycardia (Bardy et al., *N Engl J Med* 2005; 352(3): 225-237; Connolly et al., *Circulation* 2000; 101(11): 1297-1302; AVID Investigators, *N Engl J Med* 1997; 337(22): 1576-1583; Siebels and Kuck, *Am Heart J* 1994; 127(4 Pt 2): 1139-1144). ICD implantation in cardiac arrest survivors is associated with a 50% relative risk reduction for arrhythmic death and a 25% relative risk reduction for all-cause mortality (Epstein et al., *Circulation* 2013, 127: e283-352).

(27)

If ventricular fibrillation is induced during electrophysiology testing in the absence of structural heart disease and in the setting of normal ventricular function, it may not be pathologic. However, the clinical judgment of the electrophysiologist is important in determining how to interpret this finding and how to proceed with regard to implantable cardioverter defibrillator therapy.

(28)

Sustained ventricular tachycardia (VT) is defined as VT lasting greater than 30 seconds or requiring an intervention for termination (e.g., cardioversion, defibrillation) (Aliot et al., *Europace* 2009; 11(6): 771-817; Zipes et al., *Circulation* 2006; 114(10): e385-484).

(29)

The first Multicenter Automatic Defibrillator Implantation Trial (MADIT I) and the Multicenter Unsustained Tachycardia Trial (MUSTT) determined that an implantable cardioverter defibrillator (ICD) significantly reduced the incidence of sudden cardiac death in high-risk patients with inducible ventricular tachycardia (Buxton et al., *N Engl J Med* 2000; 342(26): 1937-1945; Moss et al., *N Engl J Med* 1996; 335(26): 1933-1940). A more recent study indicated that early measurement of ejection fraction after myocardial infarction, along with electrophysiological testing, provides a viable risk stratification method in identifying patients with inducible ventricular tachycardia who will benefit from ICD therapy (Zaman et al., *Circulation* 2009; 120(3): 194-200).

(30)

Nonsustained ventricular tachycardia is defined as three or more ventricular beats that terminate spontaneously within 30 seconds (Aliot et al., *Europace* 2009; 11(6): 771-817; Zipes et al., *Circulation* 2006; 114(10): e385-484).

(31)

Urgent conditions do not require preauthorization. A review to determine the appropriateness of the intervention is generally performed following the intervention.

(32)

Although clinical trials have not included patients who experience a cardiac arrest during their hospitalization for myocardial infarction (MI), the benefit of an implantable cardioverter defibrillator (ICD) for cardiac arrest survivors has been established. An ICD is recommended prior to discharge for patients who experience a cardiac arrest 48 hours after an MI as long as the arrhythmia is not due to transient or reversible ischemia (O'Gara et al., *Circulation* 2013, 127: e362-425).

(33)

Testing may be by angiogram or stress test.

(34)

If ischemia is present at stress testing, an angiogram is required to determine the severity of coronary artery disease.

(35)

Revascularization (i.e., percutaneous coronary intervention, coronary artery bypass grafting) is indicated when coronary artery stenosis is greater than or equal to 70%, fractional flow reserve is less than or equal to 0.80, or when left main stenosis is greater than or equal to 50% (Patel et al., *J Thorac Cardiovasc Surg* 2012, 143: 780-803; Hillis et al., *Circulation* 2011, 124: e652-735; Levine et al., *Circulation* 2011, 124: e574-651).

(36)

Def: Percutaneous coronary intervention (PCI) is the opening of a stenosed coronary vessel by means of balloon angioplasty, stent insertion, atherectomy, catheter thrombectomy, or a combination thereof.

(37)

A lesion may not be amenable to percutaneous coronary intervention when high risk features are present such as: length > 2 cm, high tortuosity of the proximal segment, segments with angles > 90 degrees, the inability to protect major collateral branches, and degenerated vein grafts with friable lesions. The introduction of stents has lowered the risk of technical failure (Roberts et al., *J Interv Cardiol* 2010, 23: 394-400; Krone et al., *Am J Cardiol* 2003; 92(4): 389-394).

(38)

Transient and reversible causes of ventricular arrhythmias should be ruled out prior to device placement. Examples include drug toxicity, electrolyte abnormalities, recent surgery, and myocardial ischemia (Epstein et al., *Circulation* 2013, 127: e283-352; Vardas et al., *Europace* 2007; 9(10): 959-998).

(39)

Current guidelines recommend that an implantable cardioverter defibrillator (ICD) be deferred until at least 3 months after bypass surgery or percutaneous revascularization to allow adequate time for recovery of ventricular function (Epstein et al., *Circulation* 2013, 127: e283-352). The Coronary Artery Bypass Graft (CABG) Patch trial compared prophylactic ICD implantation with no antiarrhythmic therapy at the time of coronary bypass surgery; total mortality was not significantly reduced since 71% of the deaths were nonarrhythmic (Bigger, *N Engl J Med* 1997; 337(22): 1569-1575). In the Sudden Cardiac Death in Heart Failure Trial (SCD-HeFT), patients who had their CABG more than 2 years before randomization demonstrated improved survival with an ICD (Al-Khatib et al., *J Cardiovasc Electrophysiol* 2008; 19(10): 1059-1065).

(40)

Ventricular arrhythmias in the absence of ischemic or structural heart disease are less likely to cause sudden cardiac death and should be treated with medication or ablation prior to consideration for an implantable cardioverter defibrillator.

(41)

Def: Syncope is the transient LOC and postural tone caused by diminished cerebral blood flow characterized by rapid onset, short duration, and spontaneous complete recovery.

(42)

Def: Aortic stenosis is an abnormal narrowing of the aortic valve which results in the impedance of blood flow from the left ventricle to the systemic circulation. A normal aortic valve area is >2 cm². If the valve area is between 1.5 and 2 cm², the stenosis is mild; if the valve area is between 1 and 1.5 cm², the stenosis is moderate; and if the valve area is 1 cm² or less, the stenosis is severe.

(43)

Aortic stenosis is best described as a continuum; therefore, therapeutic decisions should not be based on the degree of severity alone but correlated with the patient's symptoms.

(44)

Congenital heart disease in adults includes, most commonly, atrial septal defect, ventricular septal defect, or pulmonic stenosis. These criteria do not cover complex congenital heart disease.

(45)

The benefit of implantable cardioverter defibrillator (ICD) insertion in patients with coronary artery disease does not extend to patients with acute myocardial infarction (MI). The Defibrillator in Acute Myocardial Infarction Trial (DINAMIT) compared implantation of an ICD versus no ICD in patients who had had an acute MI and were at high risk for ventricular arrhythmias. All-cause mortality did not differ significantly between the groups. Although an ICD significantly decreased the relative risk of death due to cardiac arrhythmia compared with no ICD, it was associated with a significant increase in nonarrhythmic death (Hohnloser et al., *N Engl J Med* 2004; 351(24): 2481-2488). The Immediate Risk Stratification Improves Survival (IRIS) trial, which compared ICD therapy to medical therapy alone in patients with acute MI, validated these findings and found no evidence that early implantation of an ICD improved survival in patients with acute MI who were considered at increased risk for sudden death and were receiving optimal medical therapy (Steinbeck et al., *N Engl J Med* 2009; 361(15): 1427-1436).

(46)

Patients with a prior myocardial infarction and an ejection fraction greater than 40% are considered low risk and prophylactic implantable cardioverter defibrillator therapy is not indicated (Zipes et al., *Circulation* 2006; 114(10): e385-484).

(47)

The first Multicenter Automatic Defibrillator Implantation Trial (MADIT I) and the Multicenter Unsustained Tachycardia Trial (MUSTT) demonstrated that patients with nonsustained ventricular tachycardia, coronary artery disease, and left ventricular dysfunction (ejection fraction 40% or less) who had inducible ventricular tachycardia at electrophysiology testing were at significantly greater risk for sudden cardiac death (Buxton et al., *N Engl J Med* 2000; 342(26): 1937-1945; Moss et al., *N Engl J Med* 1996; 335(26): 1933-1940).

(48)

The Multicenter Automatic Defibrillator Implantation Trial (MADIT) II trial evaluated the potential survival benefit of prophylactic implantable cardioverter defibrillator (ICD) placement in patients with a low ejection fraction and a prior myocardial infarction. When compared with conventional medical therapy, ICD implantation was associated with a significant reduction in the risk of death (Epstein et al., *Circulation* 2013, 127: e283-352; Yancy et al., *Circulation* 2013, 128(16):e240-319; Zipes et al., *Circulation* 2006; 114(10): e385-484; Moss et al., *N Engl J Med* 2002; 346(12): 877-883).

(49)

Medical therapy may significantly improve ejection fraction (EF). Consideration of an implantable cardioverter defibrillator should follow documentation of continued worsening of EF despite a course of beta-blockers and angiotensin converting enzyme inhibitors or angiotensin II receptor antagonists (Yancy et al., *Circulation* 2013, 128(16):e240-319).

(50)

In one study, 35% of patients who had hypertrophic cardiomyopathy and received an implantable cardioverter defibrillator (ICD) for primary prevention were found to have at least one risk factor for sudden cardiac death (Maron et al., *JAMA* 2007; 298(4): 405-412). A recent systematic review of several observational studies showed a low mortality rate after ICD placement in patients with hypertrophic cardiomyopathy; patients had an average of 1.8 risk factors for sudden cardiac death (Schinkel et al., *Circ Heart Fail* 2012, 5: 552-9).

(51)

Def: A first degree relative is defined as a blood-related sibling, parent, or child.

(52)

Def: Syncope is the transient loss of consciousness and postural tone caused by diminished cerebral blood flow. It is characterized by rapid onset, short duration, and spontaneous complete recovery.

Presyncope is an episode of near-fainting or a sign of impending loss of consciousness. Symptoms include, but are not limited to, dizziness, lightheadedness, blurred vision, and general unsteadiness.

(53)

Syncope in patients with hypertrophic cardiomyopathy has been associated with an increased risk of sudden cardiac death. An observational study confirmed an association between unexplained syncope and sudden cardiac death in patients with hypertrophic cardiomyopathy. Furthermore, recent episodes of syncope were associated with a higher risk of sudden death in all age groups (Spirito et al., *Circulation* 2009, 119: 1703-10).

(54)

Evaluation of arrhythmogenic right ventricular dysplasia is considered challenging and a number of studies (e.g., electrocardiogram, transthoracic echocardiogram, MRI, biopsy) are usually required to assess for ventricular abnormalities and confirm the diagnosis.

(55)

Cardiac resynchronization therapy (CRT) is recommended for patients with New York Heart Association (NYHA) Class II heart failure (HF) and an ejection fraction (EF) \leq 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).

(56)

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).

(57)

The Defibrillators in Nonischemic Cardiomyopathy Treatment Evaluation (DEFINITE) trial demonstrated that ICD insertion significantly reduced the risk of sudden death from an arrhythmia in patients with nonischemic cardiomyopathy; however, the study failed to show a reduction in total mortality (Kadish et al., *N Engl J Med* 2004; 350(21): 2151-2158). The Sudden Cardiac Death in Heart Failure Trial (SCD-HeFT), a much larger study, found that a simple shock-only implantable cardioverter defibrillator significantly reduced the overall risk of death by 23% in patients with an ejection fraction of 35% or less due to ischemic or nonischemic cardiomyopathy (Bardy et al., *N Engl J Med* 2005; 352(3): 225-237). A recent meta-analysis supported the results of this study (Theuns et al., *Europace* 2010, 12: 1564-70).

(58)

There have been several randomized controlled trials and observational studies on the effectiveness of implantable cardioverter defibrillator (ICD) implantation in patients with nonischemic dilated cardiomyopathy. While the studies report the benefits of ICD use in these patients, there has been disagreement on duration of disease prior to ICD implantation. The Defibrillators in Nonischemic Cardiomyopathy Treatment Evaluation (DEFINITE) trial demonstrated that patients who have a recent diagnosis of nonischemic dilated cardiomyopathy receive the same benefits from ICD implantation as those with longstanding disease (Kadish et al., *J Am Coll Cardiol* 2006; 47(12): 2477-2482). Another study showed that patients with nonischemic dilated cardiomyopathy have the same rate of potentially lethal arrhythmias irrespective of disease duration (Makati et al., *Heart Rhythm* 2006; 3(4): 397-403). These findings suggest that duration of nonischemic dilated cardiomyopathy may not reliably differentiate patients at high risk for sudden cardiac death. ICD therapy can be considered in patients with nonischemic dilated cardiomyopathy as soon as they are diagnosed, as long as a reversible cause of left ventricular dysfunction is excluded (Epstein et al., *Circulation* 2013, 127: e283-352).

(59)

The Defibrillators in Nonischemic Cardiomyopathy Treatment Evaluation (DEFINITE) trial randomly assigned 458 patients with nonischemic dilated cardiomyopathy to receive standard medical therapy or standard medical therapy plus an implantable cardioverter defibrillator (ICD). The trial showed a significant reduction in the risk of sudden death from arrhythmia for those receiving medical therapy in addition to an ICD, but did not demonstrate a significant reduction in the risk of death from any cause (Kadish et al., *N Engl J Med* 2004; 350(21): 2151-2158).

ICD-9 (circle all that apply): 00.50, 00.51, 00.52, 00.54, 37.74, 37.94, 37.95, 37.96, 37.97, 37.98, 414.8, 425.11, 425.2, 425.4, 426.82, 427.0, 427.1, 427.2, 427.31, 427.32, 427.41, 427.42, 427.5, 427.60, 427.61, 427.69, 427.81, 427.89, 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, 746.89, Other_____

ICD-10-CM (circle all that apply): I25.5, I42.0, I42.2, I42.8, I46.9, I47.1, I47.2, I47.9, I49.01, I49.02, I49.1, I49.2, I49.3, I49.40, I49.49, I49.4, I49.5, I49.8, I49.9, 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, Q24.8, Other_____

ICD-10-PCS (circle all that apply): 0JH607Z, 0JH608Z, 0JH609Z, 0JH60PZ, 0JH636Z, 0JH637Z, 0JH638Z, 0JH639Z, 0JH63PZ, 0JH806Z, 0JH807Z, 0JH808Z, 0JH809Z, 0JH80PZ, 0JH836Z, 0JH837Z, 0JH838Z, 0JH839Z, 0JH83PZ, Other_____

CPT® (circle all that apply): 33202, 33203, 33216, 33217, 33224, 33225, 33230, 33231, 33240, 33249, Other_____

HCPCS (circle all that apply): C1721, C1722, C1777, C1882, C1895, C1896, G0448, Other_____