

National Imaging Associates, Inc.*	
Clinical guidelines CARDIAC RESYNCHRONIZATION THERAPY (CRT)	Original Date: February 2013
CPT Codes: 33221, 33224, 33225, 33231	Last Revised Date: March 2021
Guideline Number: NIA_CG_320	Implementation Date: January 2022

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 CARDIAC RESYNCHRONIZATION THERAPY (CRT)

(Brignole, 2013; Cleland, 2005; Epstein, 2013; Ponikowski, 2016; Russo, 2013; Yancy, 2013)

Patients with cardiomyopathy on GDMT for 3 months or on GDMT and 40 days after MI; or with implantation of pacing or defibrillation device for special indications

CRT-D Indications By NYHA Heart Failure Class (see full definitions further below in document)

- Class I: No limitation of functional activity:
 - LVEF \leq 30%, QRS \geq 150ms, LBBB, Sinus Rhythm
- Class II: Slight limitation of activity:
 - LVEF \leq 35%, QRS \geq 120ms, LBBB, Sinus Rhythm
 - LVEF \leq 35%, QRS \geq 150ms, non-LBBB, Sinus Rhythm
- Class III and Ambulatory Class IV: Severe limitation of activity but not refractory to therapy
 - LVEF \leq 35%, QRS \geq 120ms, LBBB or non-LBBB, Sinus Rhythm

Special Situations

- Independent/Regardless of NYHA Heart Failure Class
 - Patients with HFrEF (36-50%) who have an indication for ventricular pacing and high degree AV block or are expected to be paced more than 40% of the time; this includes patients with Atrial fibrillation

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- Atrial fibrillation and LVEF \leq 35% on GDMT if:
 - Patient requires ventricular pacing or otherwise meets CRT criteria; AND
 - AV nodal ablation or pharmacologic rate control will allow nearly 100% ventricular pacing with CRT
- LVEF \leq 35% and undergoing new or replacement device with anticipated requirement for significant ($>$ 40%) ventricular pacing
- In patients with nonobstructive HCM who have NYHA class II to IV heart failure with LBBB, LVEF $<$ 50%, CRT therapy for symptom reduction is reasonable

NOT Indicated for Cardiac Resynchronization Therapy (CRT)

- NYHA class I and non-LBBB pattern with QRS duration $<$ 150 ms (Epstein, 2012), except as in Special Situations section above
- Comorbidities and/or frailty expected to limit survival with good functional capacity to $<$ 1 year

Indications for CRT in Adult Congenital Heart Disease

(Hernandez-Madrid, 2018; Khairy, 2014; Stout, 2018)

Systemic LV

- Systemic LV EF \leq 35%, sinus rhythm, wide QRS complex \geq 120 ms with complete LBBB QRS morphology (spontaneous or paced) and NYHA function Class II—ambulatory IV

Any Systemic V

- Systemic ventricle any EF (not restricted to \leq 35%), intrinsic narrow QRS complex, NYHA function Class I—ambulatory IV and are undergoing new device placement or replacement with anticipated requirement for significant ($>$ 40%) ventricular pacing. Single site pacing from the systemic ventricular apex/mid-lateral wall may be considered as alternative.
- Systemic ventricle any EF (not restricted to \leq 35%), with progression of systolic systemic ventricular dysfunction and/or dilatation or expectation of such development, function Class I—ambulatory IV with a wide QRS complex \geq 150 ms (spontaneous or paced) who are undergoing other cardiac surgery, especially if thoracotomy access is needed for lead implantation

Systemic RV

- Systemic RV EF \leq 35%, wide QRS complex \geq 150 ms with a complete RBBB QRS morphology (spontaneous or paced), and NYHA function Class II – ambulatory IV

- Systemic RV EF \leq 35%, sinus rhythm, wide QRS complex (120—149 ms) with complete RBBB QRS morphology (spontaneous or paced), and NYHA function Class II—ambulatory IV
- Systemic RV and significant tricuspid valve regurgitation without a specific EF limit, wide QRS complex \geq 150 ms with a complete RBBB QRS morphology (spontaneous or paced) undergoing surgery for significant tricuspid valve regurgitation, NYHA function Class I—ambulatory IV

Single Ventricle

- Single ventricle EF \leq 35%, sinus rhythm, wide QRS complex any morphology \geq 120ms (spontaneous or paced) and NYHA function Class II—ambulatory IV

Any CHD

- CRT may be considered for patients with a severe subpulmonary RV dysfunction and dilatation despite interventions to decrease RV volume overload, NYHA function Class II—ambulatory IV and wide QRS complex \geq 150 ms due to a complete RBBB
- NYHA function Class IV and severe ventricular dysfunction who would otherwise be candidates for heart transplantation or mechanical circulatory support

NOT Indicated for CRT in Adult Congenital Heart Disease

- Patients with a narrow QRS complex ($<$ 120 ms)
- Patients whose co-morbidities and/or frailty limit survival with good functional capacity to less than 1 year

INDICATIONS FOR CRT AS THE APPROPRIATE PACING MODALITY IN SPECIAL SITUATIONS WITH $<$ 3 MONTHS OF GDMT

(Katsumoto, 2014; Marine, 2018; Russo, 2013)

Criteria are met for a non-elective implantable cardioverter defibrillator (ICD) or pacemaker, and based upon the low likelihood of improvement in symptoms and adequate recovery of LVEF, despite less than 3 months GDMT for heart failure or $<$ 40 days post myocardial infarction or 3 months post revascularization, criteria for CRT are otherwise met. This avoids a second implantation procedure within less than 3 months.

BACKGROUND

(Brignole, 2013; Epstein, 2013; Ponikowski, 2016; Russo, 2013; Yancy, 2013)

CRT, which paces the left and right ventricle in rapid sequence, also known as biventricular pacing, improves coordination of ventricular contraction in the presence of a wide QRS complex

in systolic heart failure.

CRT improves cardiac function and quality of life, and it decreases cardiac events and mortality among appropriately chosen patients. The improved survival in patients with CRT is greater than that provided by ICD insertion alone.

Guiding principles in the consideration of CRT:

- NYHA class is an important qualifying factor, with candidacy based on functional class, EF, and QRS duration.
- Bundle branch block or intraventricular conduction delay should be persistent, not rate-related (Russo, 2013).
- GDMT should have been in place continuously for at least 3 months (Epstein, 2012; Ponikowski, 2016; Yancy, 2013) and recovery of LVEF from myocardial infarction (40 days) if no intervening revascularization or > 3 months if revascularization was performed. Reversible causes (e.g., ischemia) should be excluded.
- The patient should have expected survival with reasonably good functional status for more than 1 year (Epstein, 2013; Khairy, 2014; Ponikowski, 2016).

OVERVIEW

NYHA Class Definitions

(Goldman, 1981; Russo, 2013)

- Class I: No limitation of functional activity or only at levels of exertion that would limit normal individuals (patient can carry 24 pounds up 8 stairs, play basketball, and shovel soil).
- Class II: Slight limitation of activity. Fatigue, palpitation, or dyspnea with moderate exercise (patient able to dance, garden, and walk 4 mph on level ground).
- Class III: Marked limitation of activity. Fatigue, palpitation, or dyspnea with minimal activity (patient able to shower, make bed, bowl or golf, dress, and walk 2.5 mph on level).
- Class IV: Severe limitation of activity. Symptoms even at rest, worse with activity (patient unable to comfortably perform any significant activity).
- Ambulatory Class IV: Class IV heart failure that is not refractory due to fluid retention, frequent hospitalization for heart failure, or dependent on continuous intravenous inotropic therapy.

Heart Block Definitions

(Epstein, 2013)

- First Degree: All atrial beats are conducted to the ventricles, but with a delay of > 200 ms.
- Second Degree: Intermittent failure of conduction of single beats from atrium to ventricles.

- Type I: Conducted beats have variable conduction times from atrium to ventricles.
- Type II: Conducted beats have uniform conduction times from atrium to ventricles.
- Advanced: Two or more consecutive non-conducted beats (premature atrial beats might not normally be conducted).
- Third Degree: No atrial beats are conducted from atrium to ventricle.

Guideline-Directed (or Optimal) Medical Therapy in Heart Failure

(Yancy, 2013, 2017)

- Angiotensin converting enzyme inhibitor (ACE-I), angiotensin receptor blocker (ARB), or combined angiotensin receptor inhibitor and neprilysin inhibitor (ARNI)
- Beta blocker
- Addition of loop diuretic for all NYHA class II – IV patients
- Addition of hydralazine and nitrate for persistently symptomatic African Americans, NYHA class III-IV
- Addition of an aldosterone antagonist, provided eGFR is ≥ 30 ml/min/1.73m² and K⁺ < 5.0, NYHA class II-IV
- Not required for consideration of CRT: Ivabradine for NYHA class II – III, when a beta blocker has failed to reduce a sinus rate to < 70 bpm.

Abbreviations

ACE-I	Angiotensin converting enzyme inhibitor
ARNI	Combined angiotensin receptor inhibitor and neprilysin inhibitor
AV	Atrioventricular
CAD	Coronary artery disease, same as ischemic heart disease
CHF	Congestive heart failure
CRT	Cardiac resynchronization therapy (also known as biventricular pacing)
CHD	Congenital heart disease
ECG	Electrocardiogram
EF	Ejection Fraction
eGFR	Estimated glomerular filtration rate
EPS	Electrophysiologic Study
GDMT	Guideline-Directed Medical Therapy
HCM	Hypertrophic Cardiomyopathy
HF	Heart Failure
HV	His-ventricular
ICD	Implantable cardioverter-defibrillator
LBBB	Left bundle branch block
LV	Left ventricular/left ventricle
LVEF	Left ventricular ejection fraction

MI	Myocardial infarction
ms	Milliseconds
NYHA	New York Heart Association
RBBB	Right bundle branch block
RV	Right ventricle
STEMI	ST-Elevation Myocardial Infarction
SND	Sinus node dysfunction
VT	Ventricular tachycardia

POLICY HISTORY

Date	Summary
March 2021	<ul style="list-style-type: none"> • Added indication and reference for hypertrophic cardiomyopathy with reference • Added indication for patient with expected ventricular pacing > 40% of the time • Updated /Reorganized Section: Patients with cardiomyopathy on GDMT for 3 months or on GDMT and 40 days after MI; or with implantation of pacing or defibrillation device for special indications • Updated /Reorganized Section: Indications for CRT in Adult Congenital Heart Disease • Updated Abbreviations Section
	<ul style="list-style-type: none"> • 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 • Removed comment that single site pacing from the systemic ventricular apex or mid-lateral wall may be considered as an alternative from the indication systemic ventricular EF \leq 35%, intrinsic narrow QRS complex, NYHA class I to ambulatory class IV and undergoing new or replacement device implantation with anticipated requirement for significant (>40%) ventricular pacing. • Removed the following from the Guideline Directed Medical Therapy section: Ivabradine listed as a class IIa recommendation, while others are class I recommendations. CRT trials antedated routine use of ivabradine.

August 2019

- Changed ms from 130 to 150 in indication: ‘left ventricular ejection fraction (LVEF) \leq 35%, sinus rhythm, left bundle branch block (LBBB) with a QRS \geq 150 ms, and NYHA class II, III or ambulatory class IV symptoms on GDMT’
- Added indication for LVEF \leq 35%, sinus rhythm, LBBB with a QRS duration 120 to 149 ms, and NYHA class II, III, or ambulatory class IV symptoms on GDMT
- Changed ms from 130 to 150 in indication: ‘LVEF \leq 35%, sinus rhythm, a non-LBBB pattern with a QRS duration \geq 150 ms, and NYHA III or ambulatory class IV symptoms on GDMT’
- Revised indication to state that LVEF \leq 35% and are undergoing new or replacement device placement with anticipated requirement for significant ($>$ 40%) ventricular pacing
- Removed indication for LVEF \leq 30%, ischemic etiology of HF, sinus rhythm, LBBB with a QRS duration \geq 150 ms, and NYHA class I on GDMT
- Removed indication for LVEF \leq 35%, sinus rhythm, a non LBBB pattern with a QRS duration \geq 150 ms, and NYHA class II on GDMT
- Adult congenital heart disease, added indication for systemic LVEF \leq 35%, sinus rhythm, complete LBBB with a QRS complex 120 - 149 ms (spontaneous or paced), and NYHA class II to ambulatory IV
- Adult congenital heart disease, removed the following indications:
 - Cardiac surgery with a QRS duration $>$ 150 ms
 - Systemic RV with significant tricuspid valve regurgitation
 - Severe subpulmonic RV dysfunction
 - Severe ventricular dysfunction and NYHA class IV in attempt to delay transplant or mechanical support
- The following statement has been revised to add ‘or 3 months post-revascularization.’ Criteria are met for a non-elective implantable cardioverter defibrillator (ICD) or a non-elective pacemaker, either initial or replacement, and based upon the low likelihood of improvement in symptoms and adequate recovery of LVEF, despite less than 3 months GDMT for heart failure or $<$ 40 days post myocardial infarction or 3 months post revascularization, criteria for CRT are otherwise met. The following statement has been added: ‘This avoids a second implantation procedure within less than 3 months.’

REFERENCES

Brignole M, Auricchio A, Baron-Esquivias G, et al. 2013 ESC Guidelines on cardiac pacing and cardiac resynchronization therapy, the Task Force on Cardiac Pacing and Resynchronization Therapy of the European Society of Cardiology (ESC), developed in collaboration with the European Heart Rhythm Association (EHRA). *Eur Heart J*. 2013; 34:2281–2329.

Cleland JG, Daubert JC, Erdmann E, Freemantle N, Gras D, Kappenberger L, Tavazzi L, Cardiac Resynchronization-Heart Failure (CARE-HF) Study Investigators. The effect of cardiac resynchronization on morbidity and mortality in heart failure. *N Engl J Med*. 2005; 352(15):1539.

Curtis AB, Worley SJ, Adamson PB, et al. Biventricular pacing for atrioventricular block and systolic dysfunction. *N Engl J Med*. 2013; 368:1585–1593.

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

Goldman L, Hashimoto B, Cook EF, et al. Comparative reproducibility and validity of systems for assessing cardiovascular functional class: Advantages of a new specific activity scale. *Circulation*. 1981; 64:1227.

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>

Katsumoto FM, Calkins H, Boehmer J, et al. HRS/ACC/AHA Expert Consensus Statement on the use of Implantable Cardioverter-Defibrillator therapy in patients who are not included or not well represented in clinical trials. *Heart Rhythm*. 2014; 11(7):1270-1303.

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.

Kotecha D, Flather MD, Altman DG, et al. Heart rate and rhythm and the benefit of beta-blockers in patients with heart failure. *J Am Coll Cardiol*. 2017; 69(24):2885-2896.

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*. 2018; 932-987.

Marine, JE Russo AM, Primary prevention of sudden cardiac death in heart failure and cardiomyopathy, UpToDate, Waltham, MA; May, 2018. Available at: https://www.uptodate.com/contents/primary-prevention-of-sudden-cardiac-death-in-heart-failure-and-cardiomyopathy?search=ICD%20indications§ionRank=1&usage_type=default&anchor=H957895585&source=machineLearning&selectedTitle=2~150&display_rank=2#H957895585. Retrieved June 11, 2018.

Motonaga KS, Dubin AM. Cardiac resynchronization therapy for pediatric patient with heart failure and congenital heart disease. *Circulation*. 2014; 129:1879-1891. Available at: <http://circ.ahajournals.org/content/129/18/1879.short>.

Ponikowski P, Voors AA, Anker SD, et al. 2016 ESC Guidelines for the diagnosis and treatment of acute and chronic heart failure, The Task Force for the diagnosis and treatment of acute and chronic heart failure of the European Society of Cardiology (ESC), developed with the special contribution of the Heart Failure Association (HFA) of the ESC. *Eur Heart J*. 2016; 37:2129–2200.

Russo, AM, Stainback RF, Bailey SR, et al. ACCF/HRS/AHA/ASE/HFSA/SCAI/SCCT/SCMR 2013 Appropriate Use Criteria for implantable cardioverter-defibrillators and cardiac resynchronization therapy: A report of the American College of Cardiology Foundation Appropriate Use Criteria Task Force, Heart Rhythm Society, American Heart Association, American Society of Echocardiography, Heart Failure Society of America, Society for Cardiovascular Angiography and Interventions, Society of Cardiovascular Computed Tomography, and Society for Cardiovascular Magnetic Resonance Endorsed by the American Geriatrics Society. *J Am Coll Cardiol*. 2013; 61(12):1318–1368.

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.

Stevenson WG, Hernandez AF, Carson PE, et al. Indications for cardiac resynchronization therapy: 2011 update from the Heart Failure Society of America Guideline Committee. *J Card Fail*. 2012; 18:94–106.

Stout KK, Daniels CJ, Aboulhosn JA, et al. 2018 AHA/ACC Guideline for the Management of Adults With Congenital Heart Disease: Executive Summary: A Report of the American College of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines. *J Am Coll Cardiol*. 2019; 73(12):1494-1563.

Yancy CW, Jessup M, Bozkurt B, et al. 2013 ACCF/AHA guideline for the management of heart failure: A report of the American College of Cardiology Foundation/American Heart Association Task Force on Practice Guidelines. *Circulation*. 2013; 128:e240–e327.

Yancy CW, Jessup M, Bozkurt B, et al. 2017 ACC/AHA/HFSA focused update of the 2013 ACCF/AHA guideline for the management of heart failure: A report of the American College of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines and the Heart Failure Society of America. *J Am Coll Cardiol*. 2017; 70:776–803.

Reviewed / Approved by NIA Clinical Guideline Committee

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