### 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, 2012; Ponikowski, 2016; Russo, 2013; Yancy, 2013)

- Left ventricular ejection fraction (LVEF) $\leq 35\%$, sinus rhythm, left bundle branch block (LBBB) with a QRS $\geq 150$ ms, and New York Heart Association (NYHA) class II, III, or ambulatory class IV symptoms on guideline-directed medical therapy (GDMT) (Adelstein, 2018; Ponikowski, 2016).

- 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.

- LVEF $\leq 35\%$, sinus rhythm, a non-LBBB pattern with a QRS duration $\geq 150$ ms, and NYHA class III or ambulatory class IV symptoms on GDMT (Epstein, 2012; Ponikowski, 2016; Yancy, 2013).

- 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 (Yancy, 2013).

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* National Imaging Associates, Inc. (NIA) is a subsidiary of Magellan Healthcare, Inc.
- LVEF ≤ 35% and undergoing new or replacement device with anticipated requirement for significant (> 40%) ventricular pacing (Adelstein, 2018; Brignole, 2013; Curtis, 2013; Ponikowski, 2016; Yancy, 2013).

**NOT Indicated for Cardiac Resynchronization Therapy (CRT)**

- NYHA class I or II symptoms and non-LBBB pattern with QRS duration < 150 ms (Epstein, 2012).

- 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 LVEF ≤ 35%, sinus rhythm, complete LBBB with a QRS complex ≥ 150 ms (spontaneous or paced) and NYHA class II, III, or ambulatory IV.

- Systemic LVEF ≤ 35%, sinus rhythm, complete LBBB with a QRS complex 120-149 ms (spontaneous or paced), and NYHA class II, III, or ambulatory IV.

- Systemic ventricular EF ≤ 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.

- Systemic right ventricle (RV) with an EF ≤ 35%, NYHA class II, III, or ambulatory class IV, complete right bundle branch block (RBBB) with a QRS complex ≥ 150 ms (spontaneous or paced).

- Single ventricle with an ejection fraction (EF) ≤ 35%, NYHA class II, III, or ambulatory class IV and a QRS complex ≥ 150 ms due to intraventricular conduction delay causing either a complete right or left bundle branch block morphology (spontaneous or paced).

**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, 2012; 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).

GDST 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, 2012; 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 inotrope therapy.

Heart Block Definitions
(Epstein, 2012)

- 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
eGFR  Estimated glomerular filtration rate
EPS  Electrophysiologic Study
GDMT  Guideline-Directed Medical Therapy
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
STEMI  ST-Elevation Myocardial Infarction
SND  Sinus node dysfunction
VT  Ventricular tachycardia

POLICY HISTORY:
Review Date: August 13, 2019
Review Summary:

• Changed ms from 130 to 150 in indication: ‘left ventricular ejection fraction (LVEF) ≤ 35%, sinus rhythm, left bundle branch block (LBBB) with a QRS ≥ 150 ms, and NYHA class II, III or ambulatory class IV symptoms on GDMT’
• Added indication for LVEF ≤ 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 ≤ 35%, sinus rhythm, a non-LBBB pattern with a QRS duration ≥ 150 ms, and NYHA III or ambulatory class IV symptoms on GDMT’

• Revised indication to state that LVEF ≤ 35% and are undergoing new or replacement device placement with anticipated requirement for significant (> 40%) ventricular pacing

• Removed indication for LVEF ≤ 30%, ischemic etiology of HF, sinus rhythm, LBBB with a QRS duration ≥ 150 ms, and NYHA class I on GDMT

• Removed indication for LVEF ≤ 35%, sinus rhythm, a non LBBB pattern with a QRS duration ≥ 150 ms, and NYHA class II on GDMT

• Adult congenital heart disease, added indication for systemic LVEF ≤ 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:
  o Cardiac surgery with a QRS duration > 150 ms
  o Systemic RV with significant tricuspid valve regurgitation
  o Severe subpulmonic RV dysfunction
  o 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.’

**Review Date:** March 2020

**Review Summary:**

• 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 ≤ 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 Ila recommendation, while others are class I recommendations. CRT trials antedated routine use of ivabradine.
REFERENCES:


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