MEDTRONIC DOES NOT MAKE ANY REPRESENTATIONS OR WARRANTIES IN CONNECTION WITH THE INFORMATION PRESENTED HEREIN. The information is provided for informational purposes only and is not intended as a guarantee or promise as to coverage and associated reimbursement amounts.

This information does not replace seeking advice from the payer and/or your compliance and reimbursement staff. The provider of services is ultimately responsible for compliance. FDA indications ("on-label") do not always match up with Medicare Coverage and it is entirely possible that Medicare policies limit coverage beyond the FDA label.
**FDA-Approved Indications for Medtronic CRT Devices**

Patients must meet all criteria in a given column. For CRT-D, a patient must first meet an FDA-approved ICD indication.

### Heart Failure (HF) Patients

<table>
<thead>
<tr>
<th>Device</th>
<th>CRT-D</th>
<th>CRT-P</th>
</tr>
</thead>
<tbody>
<tr>
<td>NYHA Class</td>
<td>II</td>
<td>III/IV*</td>
</tr>
<tr>
<td>LVEF</td>
<td>≤ 30%</td>
<td>≤ 35%</td>
</tr>
<tr>
<td>QRS Duration</td>
<td>LBBB**</td>
<td>Prolonged</td>
</tr>
<tr>
<td>Optimal Medical Therapy</td>
<td>Yes</td>
<td>Yes</td>
</tr>
</tbody>
</table>

### AV Block Patients***

<table>
<thead>
<tr>
<th>Device</th>
<th>CRT-D</th>
<th>CRT-P</th>
</tr>
</thead>
<tbody>
<tr>
<td>NYHA Class</td>
<td>I</td>
<td>II, III</td>
</tr>
<tr>
<td>LVEF</td>
<td>≤ 50%</td>
<td>≤ 35%</td>
</tr>
<tr>
<td>Optimal Medical Therapy</td>
<td>Yes†</td>
<td>Yes†</td>
</tr>
</tbody>
</table>

Gray shaded columns for AV block patients represent patients who meet FDA indications but do not meet Medicare covered indications for a multiple chamber defibrillator (CRT-D).

* NYHA Class IV patients should be ambulatory with no admissions for HF in the last month and have a reasonable expectation of survival.
** LBBB = Left bundle branch block.
*** Atrioventricular block (AV block) expected to require a high percentage of ventricular pacing that cannot be managed with algorithms to minimize right ventricular pacing.
† Established before implant if indicated, and should be done post-implant.

See [www.manuals.medtronic.com](http://www.manuals.medtronic.com) for complete labeling.

**Medicare Covered Indications for CRT**

- Medicare Covered Indications outline the required conditions for payment. They are distinct from manufacturer-specific FDA indications.
- All FDA-approved indications for Medtronic CRT-D devices for Heart Failure also generally meet Medicare Covered Indications. Please verify absence of exclusion criteria in the NCD 20.4.
- For FDA-approved indications for AV block patients, Medicare policies do not provide coverage for CRT-D NYHA Class I or for CRT-D patients with 35% ≤ EF ≤ 50%. Patients may still independently meet another ICD nationally covered indication. (See table of FDA-approved indications for Medtronic CRT devices for details.)
- Local Medicare Contractor policies may provide more specific guidance and are frequently updated. For further details specific to your area, and for further questions, please contact:
  - Medtronic CRDM Reimbursement Hotline: (866) 877-4102
  - rs.healthcareeconomics@medtronic.com

**Society Guidelines – Classification of Recommendations**

**Class I** Conditions for which there is evidence and/or general agreement that a given procedure or treatment is beneficial, useful, and effective.

**Class II** Conditions for which there is conflicting evidence and/or a divergence of opinion about the usefulness/efficacy of a procedure or treatment.
- **Class IIa:** Weight of evidence/opinion is in favor of usefulness/efficacy.
- **Class IIb:** Usefulness/efficacy is less well established by evidence/opinion.

**Class III** Conditions for which there is evidence and/or general agreement that a procedure/treatment is not useful/effective and in some cases may be harmful.

**Level of Evidence**

- **Level A** Data derived from multiple randomized clinical trials or meta-analyses.
- **Level B** Data derived from a single randomized trial or nonrandomized studies.
- **Level C** Only consensus opinion of experts, case studies, or standard-of-care.
2012 ACCF/AHA/HRS Guidelines for Cardiac Resynchronization Therapy

Class I Recommendations

CRT can be useful for patients who have:
- LVEF ≤ 35%
- Sinus rhythm
- Left Bundle Branch Block (LBBB)
- QRS duration ≥ 150 ms
- NYHA Class II, III, or ambulatory Class IV symptoms
- Guideline-Directed Medical Therapy (Level of Evidence: A for NYHA Class II/IV; Level of Evidence: B for NYHA Class II)

Class IIa Recommendations

CRT can be useful for patients who have:
- LVEF ≤ 35%
- Sinus rhythm
- LBBB
- QRS duration 120 to 149 ms
- NYHA Class II, III, or ambulatory Class IV symptoms
- Guideline-Directed Medical Therapy (Level of Evidence: B)

CRT can be useful for patients who have:
- Atrial fibrillation
- LVEF ≤ 35%
- Guideline-Directed Medical Therapy
If a) the patient requires ventricular pacing or otherwise meets CRT criteria and b) AV nodal ablation or pharmacologic rate control will allow nearly 100% ventricular pacing with CRT. (Level of Evidence: B)

CRT can be useful for patients who have:
- LVEF ≤ 35%
- Guideline-Directed Medical Therapy
- Anticipated requirement for significant (> 40%) ventricular pacing (Level of Evidence: C)

Guideline recommendations for patients with AV block and systolic dysfunction include the following:

- The ACC/AHA/HRS 2008 Guidelines for Device-Based Therapy of Cardiac Rhythm Abnormalities give a Class I or IIa recommendation for permanent pacing therapy for these patients.
- 2013 ACCF/AHA Guideline for the Management of Heart Failure give a Class IIa recommendation for CRT for patients on GDMT who have LVEF of 35% or less, and are undergoing placement of a new or replacement device with anticipated requirement for significant (> 40%) ventricular pacing.

Common Questions on CRT Patient Selection

1. What is the difference between guidelines and indications?
   - FDA indications are manufacturer-specific labeling approved by the FDA for use of devices
   - Medicare Covered Indications outline the required conditions for payment
   - Society guidelines provide recommendations on the use of devices in specific populations

2. Is there a Medicare National Coverage Decision for CRT?
   - No, there is not an NCD for CRT
   - CRT-D is governed by the National Coverage Decision for ICDs (NCD 20.4) as a multiple chamber defibrillator. Patients need to first meet an ICD indication.
   - CRT-P is governed at the local Medicare Contractor level

3. What needs to be documented?
   - Medicare does not define what constitutes appropriate documentation
   - Documentation may include:
     - Clinical Evaluation and Management
     - Patient characteristics (Degree of AV Block, NYHA Class, EF, QRS Width as proven through diagnostic exams)
     - Society Guideline recommendations
     - Clinical Trials supporting the decision

4. Is a CRT-D or CRT-P procedure automatically covered by Medicare if the patient meets an FDA indication?
   - No, the patient must also meet a Nationally Covered Medicare Indication (CRT-D) and/or local coverage requirements (CRT-P)

5. Is a procedure automatically covered if the patient meets a society guideline recommendation?
   - Society guidelines do not guarantee coverage but can be used as support of medical necessity in the absence of a national policy
Brief Statement: CRT ICDs and CRT IPGs

Indications
Cardiac Resynchronization Therapy (CRT) ICDs are indicated for ventricular antitachycardia pacing and ventricular defibrillation for automated treatment of life-threatening ventricular arrhythmias and for providing cardiac resynchronization therapy in heart failure patients who remain symptomatic despite optimal medical therapy if indicated, and meet any of the following classifications: New York Heart Association (NYHA) Functional Class III or IV and who have a left ventricular ejection fraction ≤ 35% and a prolonged QRS duration. Left bundle branch block (LBBB) with a QRS duration ≥ 130 ms, left ventricular ejection fraction ≤ 30%, and NYHA Functional Class II. NYHA Functional Class I, II, or III and who have left ventricular ejection fraction ≤ 50% and atrioventricular block (AV block) that are expected to require a high percentage of ventricular pacing that cannot be managed with algorithms to minimize right ventricular pacing. Optimization of heart failure medical therapy that is limited due to AV block or the urgent need for pacing should be done post-implant. Some CRT ICDs are also indicated for use in patients with atrial tachyarrhythmias, or those patients who are at significant risk for developing atrial tachyarrhythmias. The RV Lead Integrity Alert feature is intended primarily for patients who have a Medtronic ICD or CRT-D device and a Sprint Fidelis lead (Models 6949, 6948, 6931, and 6930) based on performance data. The RV LIA feature may not perform as well with a St. Jude Medical Riata™/Durata® lead or a Boston Scientific Endotak lead as it does when used with a Medtronic Sprint Fidelis lead. This is because different lead designs may have different failure signatures and conditions that may or may not be detected early by the RV LIA feature.

CRT IPGs are indicated for NYHA Functional Class III and IV patients who remain symptomatic despite stable, optimal heart failure medical therapy and have a LVEF ≤ 35% and a prolonged QRS duration and for NYHA Functional Class I, II, or III patients who have a LVEF ≤ 50%, are on stable, optimal heart failure medical therapy if indicated and have atrioventricular block (AV block) that are expected to require a high percentage of ventricular pacing that cannot be managed with algorithms to minimize right ventricular pacing. Optimization of heart failure medical therapy that is limited due to AV block or the urgent need for pacing should be done post-implant. Rate adaptive pacing is provided for those patients who cannot tolerate pacing rates above the programmed Lower Rate. Dual chamber sequential pacing is contraindicated in patients with chronic or persistent supraventricular tachycardias, including atrial fibrillation or flutter. Asynchronous pacing is contraindicated in the presence (or likelihood) of competition between paced and intrinsic rhythms. Single chamber atrial pacing is contraindicated in patients with an AV conduction disturbance. Antitachycardia pacing (ATP) therapy is contraindicated in patients with an accessory antegrade pathway.

Warnings/Precautions
Changes in a patient’s disease and/or medications may alter the efficacy of the device’s programmed parameters. Patients should avoid sources of magnetic and electromagnetic radiation to avoid possible underdetection, inappropriate sensing and/or therapy delivery, tissue damage, induction of an arrhythmia, device electrical reset, or device damage. Do not place transvenous defibrillation paddles directly over the device. Certain programming and device operations may not provide cardiac resynchronization. Also for CRT IPGs, Elective Replacement Indicator (ERI) results in the device switching to VVI pacing at 65 ppm. In this mode, patients may experience loss of cardiac resynchronization therapy and/or loss of AV synchrony. For this reason, the device should be replaced prior to ERI being set.

Potential Complications
Potential complications include, but are not limited to, rejection phenomena, erosion through the skin, muscle or nerve stimulation, oversensing, failure to detect and/or terminate arrhythmia episodes, and surgical complications such as hematoma, infection, inflammation, and thrombosis. An additional complication for CRT ICDs is the acceleration of ventricular tachycardia. See the device manual for detailed information regarding the implant procedure, indications, contraindications, warnings, precautions, and potential complications/ adverse events. For further information, please call Medtronic at 1 (800) 328-2518 and/or consult Medtronic’s website at www.medtronic.com.

Caution: Federal law (USA) restricts these devices to sale by or on the order of a physician.

References
2. ACC/AHA/HRS 2008 Guidelines for Device-Based Therapy of Cardiac Rhythm Abnormalities: http://circ.ahajournals.org/content/117/21/e350
3. 2013 ACCF/AHA Guideline for the Management of Heart Failure: http://circ.ahajournals.org/content/early/2013/06/03/CIR.0b013e31829e8776.citation