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APPROPRIATE USE CRITERIA

ACC/AHA/ASE/HFSA/HRS/SCAI/SCCT/SCMR 2025 Appropriate Use Criteria for Implantable Cardioverter-Defibrillators, Cardiac Resynchronization Therapy, and Pacing

A Report of the American College of Cardiology Solution Set Oversight Committee, American Heart Association, American Society of Echocardiography, Heart Failure Society of America, Heart Rhythm Society, Society for Cardiovascular Angiography and Interventions, Society of Cardiovascular Computed Tomography, and Society for Cardiovascular Magnetic Resonance

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ABSTRACT

This appropriate use criteria (AUC) document is developed by the American College of Cardiology along with key specialty and subspecialty societies. It provides a comprehensive review of common clinical scenarios where implantable cardioverter-defibrillator (ICD), cardiac resynchronization therapy (CRT), cardiac contractility modulation, leadless pacing, and conduction system pacing therapies are frequently considered. The 335 clinical scenarios covered in this document address ICD indications including those related to secondary prevention, primary prevention, comorbidities, generator replacement at elective replacement indicator, dual-chamber, and totally subcutaneous ICDs, as well as device indications related to CRT, conduction system pacing, leadless pacing, cardiac contractility modulation, and ICD therapy in the setting of left ventricular assist devices (LVADs).

The indications (clinical scenarios) were derived from common applications or anticipated uses, as well as from current clinical practice guidelines and results of studies examining device implantation. The indications in this document were developed by a multidisciplinary writing group and scored by a separate independent rating panel on a scale of 1 to 9 to designate care that is considered “Appropriate” (median 7 to 9), “May Be Appropriate” (median 4 to 6), and “Rarely Appropriate” (median 1 to 3). The final ratings reflect the median score of the 17 rating panel members.

In general, Appropriate designations were assigned to scenarios for which clinical trial evidence and/or clinical experience was available that supported device implantation. In contrast, scenarios for which clinical trial evidence was limited or device implantation seemed reasonable for extenuating or practical reasons were categorized as May Be Appropriate. Scenarios for which there were data showing harm, or no data were available, and medical judgment deemed device therapy was ill-advised were categorized as Rarely Appropriate. For example, comorbidities including reduced life expectancy related to noncardiac conditions or severe cognitive

dysfunction would negatively impact appropriateness ratings.

The appropriate use criteria for ICD, CRT, and pacing have the potential to enhance clinician decision making, healthcare delivery, and payment policy. Furthermore, recognition of clinical scenarios rated as May Be Appropriate facilitates the identification of areas where there may be gaps in evidence that would benefit from future research.

PREFACE

The American College of Cardiology (ACC) has a long history of developing documents (eg, expert consensus decision pathways, health policy statements, AUC documents) to provide members with guidance on both clinical and nonclinical topics relevant to cardiovascular care. In most circumstances, these documents have been created to complement clinical practice guidelines and to inform clinicians about areas where evidence is new and evolving or where sufficient data are more limited. Despite this, numerous gaps persist, highlighting the need for more streamlined and efficient processes to implement best practices in patient care.

Central to the ACC's strategic plan is the generation of *actionable knowledge*—a concept that places emphasis on making clinical information easier to consume, share, integrate, and update. To this end, the ACC has shifted from developing isolated documents to creating integrated "solution sets." These are groups of closely related activities, policy, mobile applications, decision-support tools, and other resources necessary to transform care and/or improve heart health. Solution sets address key questions facing care teams and attempt to provide practical guidance to be applied at the point of care. They use both established and emerging methods to disseminate information for cardiovascular conditions and their related management. The success of solution sets rests firmly on their ability to have a measurable impact on the delivery of care. Because solution sets reflect current evidence and ongoing gaps in care, the associated tools will be refined across time to match changing evidence and member needs.

AUC represent a key component of solution sets. They consist of common clinical scenarios associated with given disease states and ratings that define when it is reasonable to perform testing or provide therapies and, importantly, when it is not. AUC methodology relies on content development work groups, which create patient scenarios, and independent rating panels that employ a modified Delphi process to rate the relevant options for testing and intervention as Appropriate, May Be Appropriate, or Rarely Appropriate. AUC should not replace clinician judgment and practice experience but should function as tools to improve patient care and health outcomes in a cost-effective manner.

I extend sincere gratitude to the writing group for their invaluable contributions to the development of this document's structure and clinical scenarios; to the rating panelists—a distinguished group of professionals with diverse expertise—for their thoughtful deliberation of the merits of device implantation across various clinical contexts; and to the reviewers for their thoughtful evaluation of the clinical scenarios and evidence mapping. Additionally, I am grateful to the members of the Solution Set Oversight Committee, which provided insight and guidance, and to ACC staff members María Velásquez and Lara Gold, for their support in bringing this document to fruition.

Nicole M. Bhave, MD, FACC
Chair, ACC Solution Set Oversight Committee

1. INTRODUCTION

This updated AUC document focuses on cardiac implantable electronic devices (CIEDs), highlighting clinical areas for which new information is available or changes in practice have occurred since publication of the 2013 document,[1] which includes new procedures and technologies that have become more readily available or approved by the U.S. Food and Drug Administration (FDA) since then. Specifically, this includes sections dedicated to conduction system pacing (His bundle pacing [HBP] or left bundle area pacing), leadless pacing, and cardiac contractility modulation (CCM). Technologies that were not yet approved by the FDA when the rating panel met (eg, extravascular ICDs) are not included in this document. The writing group also thought it was important to add additional heart failure (HF) sections that include LVADs and devices following cardiac transplantation, because these scenarios may include complexities related to ICD indications and device management. In addition to developing many new scenarios, the writing group reviewed all scenarios from the 2013 document, and those that remain current were not changed; however, due to the duration of time since the last publication, the rating panel was asked to vote on all scenarios to determine whether there were any changes in practice that would impact on the ratings.

While guideline documents provide recommendations that include evidence available from clinical trials, it is recognized that gaps exist and "real-world" practice includes many scenarios that cannot be incorporated in guideline documents. AUC documents can help address these patient populations that are either not represented in currently available clinical trials or treatment recommendations that may be supported by lower levels of evidence. In addition, it is important to recognize that

when patients are excluded from a clinical trial, the result of the trial should not be interpreted to mean that the treatment was proven to be ineffective for patients who were excluded. Clinicians should use their best judgment in deciding whether a treatment might be beneficial to patients who were excluded from trial enrollment.

During development of this document, rapid advancements in leadless and physiological pacing have occurred, and the writing group recognizes that ratings for these scenarios represent only a single point in time. It is anticipated that an evolution of pacing indications will continue to occur with time as research and technology further expand.

The AUC were designed to include a broad spectrum of clinical scenarios representative of those encountered in daily practice. Because ICDs, CRT, and pacing play a central role in the care of patients with cardiovascular disease and often involve complex decision making, guidance around the rationale and practical use of device implantation is the goal of the current document.

2. METHODS

To begin the AUC process, a writing group of multidisciplinary experts from several cardiovascular subspecialty societies and American College of Cardiology (ACC) Councils was formed to identify and categorize common clinical scenarios. Members of the writing group and the rating and review panels were selected in large part because of their active involvement in the clinical practice of electrophysiology, HF, and other related areas of cardiovascular medicine. The writing group focused on choosing the most common situations encountered in daily practice because it would be impossible to cover every possible patient presentation without making the list excessively long. Whenever possible during the writing process, the group members would map the indications to relevant guidelines, clinical trials, and other key references (Guideline Mapping Online Appendix). It should be noted that the term "indication" is used interchangeably with "clinical scenario" in this document and does not imply that a procedure should necessarily be performed. The indications included in this publication incorporate a wide range of cardiovascular symptoms, disease states, and physiological assessments, including but not limited to measurements of left ventricular ejection fraction (LVEF), HF functional class, duration of the QRS complex, monitoring data, and results of electrophysiological studies. Once the indications were drafted, they were reviewed and critiqued by numerous external reviewers representing a variety of cardiovascular subspecialty societies and ACC Councils.

After the writing group incorporated this initial feedback from the reviewers, the indications were sent to an independent rating panel comprised of additional experts, along with a Guideline Mapping document for its reference. The rating panel was asked to independently evaluate the clinical scenarios, assessing the benefits and risks of the device implantation scenarios. The panel then convened for a virtual meeting to discuss each clinical scenario. Before the meeting, panel members were given their scores and a blinded summary of their peers' scores. Following this group discussion of the indications and related considerations, subsequent individual ratings were again performed. As the "2023 HRS/APHRS/LAHRS Guideline on Cardiac Physiologic Pacing for the Avoidance and Mitigation of Heart Failure"[2] was underway during development and was published prior to completion of this AUC document, the rating panel was reconvened for reassessment of the clinical scenarios related to novel atrioventricular (AV) conduction system pacing (Section 12). This guideline was included in the Guideline Mapping document and the rating panel was given the opportunity to rate these scenarios covered in that document and these final scores are included in the current document.

A detailed description of the methods used for rating the clinical scenarios can be found in previous ACC AUC methodology publications, including the 2018 methodology update paper.[3] This process combines evidence-based medicine and practice experience and engages a rating panel in a modified Delphi exercise.[3] For the scoring, care is taken to provide the rating panel with objective, unbiased information, including guidelines and key references in the field (Guideline Mapping Online Appendix).

In scoring the clinical scenarios, the rating panelists were asked to assess whether it is Appropriate, May Be Appropriate, or Rarely Appropriate to implant a device given the specific patient scenario. When scoring the indications, panel members are asked to use the following definition of appropriate use:

An Appropriate procedure is 1 in which the potential benefits, in terms of survival and/or other health benefits (symptoms, functional status, and/or quality of life [QOL]), exceed the potential adverse health consequences related to the acute procedural risk and the long-term consequences of living with an implanted device.

The panel members scored the scenarios according to the following scale:

Score 7 to 9: *Appropriate care* for specific indication (generally acceptable and reasonable approach for the indication). ***An appropriate option*** *for management of patients in this population due to* ***benefits generally outweighing risks****; effective option for individual care plans although not always necessary depending on clinician judgment and patient-specific preferences (ie, generally acceptable and generally reasonable for the indication).*

Score 4 to 6: ***May Be Appropriate care*** for specific indication (**may** be generally acceptable and **may** be a reasonable approach for the indication). May Be Appropriate also may imply that more research and/or patient information is needed to classify the indication definitively. ***At times an appropriate option*** *for management of patients in this population due to variable evidence or agreement regarding the benefits/risks ratio, potential benefit based on practice experience in the absence of evidence, and/or variability in the population; effectiveness for individual care must be determined by a patient's clinician in consultation with the patient based on additional clinical variables and judgment along with patient preferences (ie, may be acceptable and may be reasonable for the indication).*

Score 1 to 3: ***Rarely Appropriate care*** for specific indication (**not** generally acceptable and **not** a reasonable approach for the indication). ***Rarely an appropriate option*** *for management of patients in this population due to the lack of a clear benefit/risk advantage; rarely an effective option for individual care plans; exceptions should have documentation of the clinical reasons for proceeding with this care option (ie, not generally acceptable and not generally reasonable for the indication).*

The division of the numerical scores into 3 levels of appropriateness is somewhat arbitrary, and the numerical designations should be viewed as a continuum. It is important to note that there may be diversity in clinical opinion for particular clinical scenarios, such that scores in the intermediate level of appropriate use should be labeled May Be Appropriate, because critical patient or research data may be lacking or discordant. This designation should serve as a prompt to carry out definitive research in this field whenever possible.

The scenarios included in this document are based on our current understanding of patient outcomes plus the potential benefits compared with risks of the treatment strategies involved. Each patient should be treated individually based on their own particular needs at a given point in time. It is also expected that clinicians will occasionally care for patients with unique conditions that could result in a Rarely Appropriate score. When this occurs, clinicians should document the specific situation and patient characteristics, but it should not be used as a deterrent for treating the patient or denial of payment. While a Rarely Appropriate designation should not prevent a treatment from being performed, an Appropriate designation is also not a requirement or "must do" for a given treatment. The AUC are offered to help guide patient care but should not be considered a substitute for sound clinical judgment and practice experience.

3. ASSUMPTIONS

To limit inconsistencies in interpretation, specific assumptions were developed by the writing group when creating scenarios, and these assumptions were used by the rating panel in scoring the clinical indications for the appropriate use of device implantation.

General Clinical Assumptions

1. For each indication, the rating should reflect whether device implantation is reasonable for the patient according to the appropriate use definition.
2. A qualified clinician has completed a thorough clinical history and physical examination such that the clinical status of the patient can be assumed to be valid as stated in the indication. It is also assumed that the procedures are ordered by clinicians knowledgeable in ICD/CRT/pacing indications and the procedures are performed and interpreted by qualified personnel in facilities compliant with national standards.
3. End-of-life discussion, advanced directive, and patient consent have been adequately addressed. Patients are assumed to be candidates for ICD/CRT/pacing only after shared decision making has been undertaken between the patient and the clinician, including family and/or legal decision makers when appropriate.
4. The clinical scenarios should be preferentially rated based on evidence from published literature and clinical practice guidelines regarding the risks and benefits of ICD/CRT/pacing.[4-8] Selected specific patient groups not well represented in the literature or in clinical practice guidelines are presented in many of the current clinical scenarios because the writing group recognizes that decisions about device implantation in such patients are frequently required despite gaps in available evidence.
5. All patients are receiving optimal care, also called "guideline-directed medical therapy" (GDMT) in clinical practice guidelines. This includes GDMT and guideline-based risk factor modification for primary or secondary prevention for coronary artery disease (CAD) and HF in cardiovascular patients unless specifically noted.[9-13]
6. There are no unusual extenuating logistical or process of care circumstances such as inability to comply with follow-up due to any number of reasons (eg, mental instability, lack of transportation) unless specifically noted.
7. There are no patient-specific technical limitations for device implantation or other comorbidities that are likely to substantially increase procedural risk, unless specifically noted.

8. CAD: For sections that reference revascularization, additional assumptions may apply, including but not limited to the following:
   a. For scenarios in which no revascularization is planned, it should be assumed that revascularization is not indicated unless otherwise specified, eg, there are no major epicardial coronary lesions measuring ≥70% (non-left main) or ≥50% (left main) or no evidence of ischemia by fractional flow reserve or perfusion imaging.
   b. Other scenarios may include cases where patients are not candidates for revascularization for whatever reason, including but not limited to severe, diffuse CAD that is not amenable with revascularization.
   c. When revascularization is considered or performed, it is assumed that patients are acceptable candidates for revascularization based on the absence of other noncardiac comorbidities that would be a contraindication for revascularization.
   d. If patients are candidates for revascularization and revascularization is planned, electrophysiology (EP) testing should not be performed until the appropriate timing after the intended revascularization procedure is performed.
   e. An ICD should not be implanted before revascularization to circumvent the current Centers for Medicare and Medicaid Services' 3-month waiting-period rule.[14]
   f. Regardless of whether revascularization is performed, GDMT for HF should be administered in the setting of CAD and reduced left ventricular (LV) systolic function.
9. An assessment of the LVEF during hospitalization following acute infarction or revascularization generally prompts consideration of ICD/CRT implantation. When a subsequent waiting period is required (eg, after GDMT, myocardial infarction [MI], or revascularization), it is assumed that the final decision to treat will be based on a follow-up LVEF assessment after expiration of the waiting period. For all indications, it is assumed that the LVEF stated in the indications was measured within a time frame relevant to making the decision about eligibility for ICD implantation.
10. With respect to CRT indications, it is assumed that sinus rhythm is present unless otherwise specified that atrial arrhythmias are present; however, it is assumed that the presence of intermittent or persistent atrial arrhythmias would not preclude CRT implantation, and the benefits of CRT would also apply to patients with persistent atrial arrhythmias, as long as CRT is maintained ≥98% of the time.[15,16]
11. The potential adverse effects of right ventricular (RV) pacing in the setting of pre-existing LV systolic dysfunction are well described.[17-21] Therefore, attempts should be made to reduce unnecessary RV pacing by appropriate programming of single- and dual-chamber ICDs or pacemakers (PMs), whenever possible. The use of cardiac physiological pacing using conduction system pacing or CRT may be considered as an alternative to ventricular pacing avoidance algorithms in certain situations.
12. Single- vs dual-chamber ICD selection: It is assumed that most patients undergoing ICD implantation who have standard dual-chamber pacing indications will undergo attempted insertion of an atrial lead as described in the 2012 HRS/American College of Cardiology Foundation Expert Consensus Statement on Pacemaker Device and Mode Selection.[22] However, there is currently controversy regarding single- vs dual-chamber device selection in patients who do not meet strict pacing indications but are undergoing ICD implantation without CRT. Because there is a difference in cost, complication rates, and a potential difference in longevity of single- vs dual-chamber devices, without clear benefit of dual-chamber systems in discrimination between ventricular and supraventricular arrhythmias, these scenarios were felt to be important to address in this document.[23-27]
13. Decisions for ICD implantation should be based on a reasonable expectation of survival with a good functional status for ≥1 year. The clinical trial populations used to derive published predictive survival models may differ from the general HF population with regard to age and comorbidities. Therefore, consideration should be given to advanced age or other comorbidities that might reduce the likelihood of benefit or increase the risk of ICD therapy.[28,29]

Practice Parameters/Standard of Care

14. Operators performing device implantation have appropriate clinical training[30] and experience consistent with established standards of care and have satisfactory outcomes as assessed by quality assurance monitoring, such as national benchmark data from the National Cardiovascular Data Registry (NCDR) ICD Registry (now NCDR EP Device Implant Registry).[31] CIEDs are implanted with transvenous electrodes unless implantation of a totally subcutaneous ICD or leadless pacing is specifically noted. Because the extravascular ICD was not approved by the FDA at the time of development of this document, potential scenarios utilizing this device are not included in this AUC document. Appropriate training applies to standard devices as well as new technology

or techniques, including leadless pacing and physiological pacing.

15. It is assumed that skilled operators and appropriate implantation resources are locally available to perform CIED implantation procedures.
16. Adjunctive cardiac imaging modalities are often required for appropriate patient selection. These may include coronary angiography, cardiac computed tomography, echocardiography, cardiac magnetic resonance imaging, and radionuclide imaging. It assumed that laboratories performing these services have appropriate clinical training and experience, perform these studies, and interpret them according to national standards, and have satisfactory outcomes as assessed by quality improvement monitoring.
17. It is recognized that there may be variability in the measurement of LVEF utilizing different imaging modalities. It is assumed that echocardiograms used for decision making provide a quantitative output and not just a qualitative or semiqualitative assessment. The laboratories performing LVEF assessments will have quality assurance measures in place to ensure accuracy of each individual method for determining and reporting LV function.
18. All procedures are presented for clinical indications and not as part of a research protocol.

Cost/Value

19. From the standpoint of the practicing clinician caring for an individual patient, potential clinical benefits of device implantation must be weighed against potential risks of the procedure. As related to societal benefits, costs should also be considered in relationship to potential benefits to better understand comparative value. Although cost and value are clearly important factors, which are also relevant to payers and policymakers, it is recognized that healthcare providers typically do not primarily base individual patient decisions about device implantation on these considerations. Therefore, it is anticipated that panel members will rate the scenarios primarily based on risks-benefits, although cost/value considerations may also be taken into consideration if deemed Appropriate by panel members for particular scenarios.

Guidance Specifically for AUC Users

20. Reducing care that is Rarely Appropriate remains a valuable means of reducing costs and population risks of ICD/CRT/PM implantation.
21. The category of May Be Appropriate should be used when insufficient clinical data are available for a definitive categorization or there are substantial differences in opinion regarding the appropriateness of that indication. The absence of definitive data supporting implantation in a particular subset of patients does not imply lack of benefit, and in such cases careful assessment of the particular clinical scenario is warranted. The designation of May Be Appropriate should not be used as the sole grounds for denial of payment in an individual patient.

4. DEFINITIONS

Definitions of terms used throughout the indication set are listed here.

HF duration: The duration of HF symptoms is defined as the duration of symptoms since the initial diagnosis of HF to the date of device implantation. Clinical trials and the NCDR ICD (EP Device Implant) Registry have utilized time frames of <3, 3 to 9, and >9 months. The committee recognizes that 3 months may equate to more or less than 90 days, depending on the calendar months. The 3-month term was chosen since it was used in some randomized clinical trials related to timing for device implantation and is the basis of coverage in the Centers for Medicare and Medicaid Services National Coverage Determination for nonischemic dilated cardiomyopathy (CM).[14]

GDMT for HF: GDMT (sometimes referred to as "optimal medical therapy") for HF in the setting of LV systolic dysfunction requires individualization but ideally should include the combination of an angiotensin-converting enzyme inhibitor or angiotensin receptor blocker, a beta-blocker, mineralocorticoid antagonist (MRA), and a sodium-glucose cotransporter 2 inhibitor (SGLT2i).[32,33] Therapy should be adjusted to target doses as tolerated. Sacubitril/valsartan is indicated for patients with New York Heart Association (NYHA) functional class II to IV HF.[12,13] Ivabradine should be considered in patients in sinus rhythm who remain with elevated heart rates (>70 beats/min) after maximally tolerated beta-blocker dose.[12] Diuretics are adjusted if/as needed to control fluid retention. In selected patients, the addition of aldosterone antagonists and hydralazine plus nitrate combinations should be considered. Patients who are going to receive substantial benefit from medical treatment alone usually show some clinical improvement during the first 3 to 6 months. Medical therapy is also assumed to include adequate rate control for tachyarrhythmias, including atrial fibrillation. Therefore, it is recommended that GDMT be provided for ≥3 months before planned reassessment of LV function to consider device implantation. If LV function improves to the point where primary prevention indications no longer apply, then device implantation is not indicated.

HF: The "universal definition of heart failure" is a "clinical syndrome with symptoms and/or signs caused by a structural and/or functional cardiac abnormality and corroborated by elevated natriuretic peptide levels and/or

objective evidence of pulmonary or systemic congestion."[34] The clinical symptoms of HF may include dyspnea on exertion, orthopnea, fatigue, or fluid retention. The clinical signs may include jugular venous pressure elevation, rales, an S3 gallop, and/or lower extremity edema. A low LVEF or diagnosis of CM alone, or peripheral edema without other clinical signs of HF, does not qualify as clinical HF.[12,13,35,36]

Hemodynamic instability: Patients may experience periods of clinical instability with hypotension, HF symptoms, presyncope, syncope, angina, or dyspnea. These symptoms are presumed to result from hypoperfusion, with a cardiac output and/or rhythm that is inadequate to support normal organ function.

Inducibility at EP testing: Inducibility is defined as the induction of sustained ventricular tachycardia (VT) or ventricular fibrillation (VF) at EP testing with an arrhythmia duration (≥30 seconds) or resulting in hemodynamic compromise requiring earlier intervention (<30 seconds) using standardized stimulation protocols.

MI: The "Universal Definition of Myocardial Infarction" was developed by Thygesen and colleagues, with its most recent updates in 2012 and 2018.[37,38] The multifaceted clinical criteria include timing, mechanism (infarct type), biomarker status, and size. An elevated troponin is not necessarily indicative of an acute MI.[37-39]

MI (type 1) vs nonspecific low-level troponin elevation: Not infrequently, a low-level troponin elevation is detected when blood is drawn routinely or as a consequence of protocol laboratory testing. If upon further evaluation the troponin levels do not exhibit a typical rise and fall pattern, or there is an alternative explanation for the troponin leak (eg, cardiac arrest or external defibrillation) that can be explained by a diagnosis other than myocardial ischemia, this should not be misconstrued as a type 1 MI (as defined by Thygesen et al[37,38] and due to atherothrombotic CAD) based on the laboratory test alone.[40] Importantly, in conjunction with cardiac arrest a nonspecific, transient low-level rise in troponin with subsequent fall, in the absence of CAD or thrombosis may occur. This should not be considered a type 1 MI because the arrest itself may lead to a leak of troponin likely related transient absent coronary blood flow and ischemia resulting from the arrest itself. These low-level rises in biomarkers should not preclude ICD implantation, if criteria for implantation are otherwise met. These criteria are all based on the presence of type 1 MI, not type 2 MI in which ischemic myocardial injury occurs because of mismatch between oxygen supply and demand.

NYHA functional classification: The definitions are included in **Table 1** below. The patient's NYHA functional classification at the time of the decision to implant the device should be used for this classification. If the patient has LV dysfunction, but no symptoms of HF, this should be coded as "class I." If the patient is hospitalized for HF at the time the decision is made to implant the device, the NYHA functional class on optimized GDMT should be utilized.

TABLE 1. NYHA Functional Classification

Class I	No limitation of physical activity. Ordinary physical activity does not cause undue fatigue, palpitation, or dyspnea.
Class II	Slight limitation of physical activity. Comfortable at rest. Ordinary physical activity results in fatigue, palpitation, or dyspnea.
Class III	Marked limitation of physical activity. Comfortable at rest. Less than ordinary activity causes fatigue, palpitation, or dyspnea.
Class IV	Unable to carry on any physical activity without discomfort. Symptoms of heart failure may be present even at rest. If any physical activity is undertaken, discomfort is increased.

Adapted from Yancy et al.[13]
NYHA = New York Heart Association.

Ambulatory NYHA functional class IV: Ambulatory class IV is defined as class IV HF with the following: 1) no active acute coronary syndrome; 2) no inotropes; and 3) on GDMT.

Normal LVEF: A normal LVEF is defined as ≥50%.

Secondary prevention (Section 1 indications): Secondary prevention refers to an indication for an ICD exclusively for patients who have survived ≥1 cardiac arrests or episode(s) of sustained VT or VF. Ventricular arrhythmias are considered sustained if they last ≥30 seconds or result in hemodynamically significant symptoms prior to that time (ie, requiring cardioversion or defibrillation). Patients with cardiac conditions associated with a high risk of sudden cardiac death (SCD) who have unexplained syncope presumed to be the result of self-terminating ventricular arrhythmias are also considered to have a secondary prevention indication.

Primary prevention (Section 2 indications): Primary prevention is an indication for an ICD to prevent SCD. It refers to use of ICDs in individuals who are at risk for, but have not yet had, an episode of sustained VT, VF, or cardiac arrest.

QRS duration: A "narrow" QRS duration is <120 ms. A wide QRS is ≥120 ms and may have a left bundle branch block (LBBB), right bundle branch block (RBBB), or nonspecific intraventricular conduction delay (IVCD) morphology. For the purpose of this AUC document and for consistency with the Focused Update of the Device-Based Guidelines, "non-LBBB" morphology is used to refer to both RBBB and IVCD morphologies. For the purpose of CRT implantation, it is assumed that the wide QRS is present consistently and does not represent an intermittent bundle branch block or intermittent QRS

widening, thereby excluding QRS widening that is transient or rate related. If there is discrepancy in the measurement of QRS duration on various electrocardiograms (ECGs), the most representative ECG obtained proximate to the final clinical decision-making process will be utilized to determine candidacy for CRT implantation.

Structural heart disease: This refers to conditions or disorders related to the heart's structure, including heart muscle or valves. Genetic arrhythmia diseases related to only the ECG are not included, but those associated with CM are in the definition of structural heart disease. Coronary atherosclerosis, unassociated with myocardial dysfunction, is not included.

Sudden cardiac arrest: Sudden cardiac arrest is defined as the sudden cessation of effective cardiac mechanical activity resulting in unresponsiveness, without normal breathing or signs of circulation. If corrective measures are not rapidly taken, this progresses to sudden death. Sudden cardiac arrest should be used to signify an event that is reversed, usually by cardiopulmonary resuscitation and/or defibrillation, cardioversion, or cardiac pacing. The mechanism for a tachyarrhythmic arrest may be due to VT or VF, or VT degenerating into VF.

Syncope: Syncope is defined as a sudden loss of consciousness with the inability to maintain postural tone, not related to anesthesia or a seizure disorder, with spontaneous recovery reported by the patient or an observer. This excludes cardiac arrest, which requires resuscitation.

Timing post-MI: For the purpose of this AUC document:

- "**Acute MI**" is defined as ≤48 hours after the onset of symptoms;
- "**Recent post-MI**" is defined as ≤40 days after the onset of acute MI symptoms.[6,41]

Ventricular arrhythmias prior to generator replacement: As part of ICD follow-up care, decisions must be made regarding the need for generator replacement at the time of battery depletion. In addition to assessing for PM dependency, the presence or absence of ICD therapy for ventricular arrhythmias might be taken into account when considering the need for replacement, particularly if new comorbidities have developed that may otherwise have an impact on life expectancy.

Clinically relevant ventricular arrhythmias in an ICD recipient refer to:

a. VT leading to antitachycardia pacing or VT/VF leading to shock therapy, or
b. VT duration ≥30 seconds in a monitor-only zone (or <30 seconds associated with hemodynamically significant symptoms), or
c. VT lasting ≥30 seconds at a rate near the tachycardia-detection threshold but not receiving therapy due to only intermittent detection.

In the case of antitachycardia pacing (ATP) therapy for VT, it is recognized that many of these episodes might have spontaneously terminated if detection were delayed. "Nonsustained ventricular tachycardia" (NSVT) is VT lasting <30 seconds that spontaneously terminates prior to delivery of device therapy (including either ATP or shock therapy). It is recognized that implanting clinicians will have a variety of different programming preferences, and some of these may include a monitor zone or prolonged detection duration to minimize appropriate or inappropriate therapy for arrhythmias that may spontaneously terminate as outlined in consensus statement recommendations.[16]

VF: VF is a cardiac arrhythmia arising from the ventricles that occurs when the heart's electrical activity becomes disordered and rapid. VF is not synonymous with device-defined VF, as the device defines VT and VF solely based on the programmed detection rate and does not consider the morphology of the arrhythmia.

VT: VT is a cardiac tachyarrhythmia of ≥3 consecutive complexes in duration emanating from 1 of the ventricles with a rate of ≥100 beats/min. It can be "sustained" or "nonsustained."

VT, sustained: Sustained VT is defined as VT lasting ≥30 seconds or terminated by cardioversion or pacing prior to that time.

VT, hemodynamically significant: Hemodynamically significant VT is defined as VT of any duration that results in hypotension or hemodynamically significant symptoms such as angina, dyspnea, lightheadedness, presyncope, or syncope.

VT, nonsustained, not hemodynamically significant (asymptomatic NSVT): NSVT is defined as ≥3 consecutive premature ventricular complexes but lasting <30 seconds and spontaneously terminating, without associated hemodynamically significant symptoms, and rate ≥100 beats/min.

5. ABBREVIATIONS

6MWT = 6-minute walk test
A = Appropriate
ACC = American College of Cardiology

AHA = American Heart Association
APHRS = Asia Pacific Heart Rhythm Society
ATP = antitachycardia pacing
AUC = appropriate use criteria
AV = atrioventricular
B-NR = B-nonrandomized
BiV = biventricle
C-LD = C-limited data
CABG = coronary artery bypass graft surgery
CAD = coronary artery disease
CAV = cardiac allograft vasculopathy
CCM = cardiac contractility modulation
CIED = cardiovascular implantable electronic device
CKD = chronic kidney disease
CM = cardiomyopathy
CRT = cardiac resynchronization therapy
CRT-D = cardiac resynchronization therapy with defibrillator
CS = coronary sinus
CSP = conduction system pacing
ECG = electrocardiogram
EF = ejection fraction
EPS = electrophysiological study
FDA = U.S. Food and Drug Administration
GDMT = guideline-directed medical therapy
HBP = His bundle pacing
HF = heart failure
HR = hazard ratio
HRS = Heart Rhythm Society
ICD = implantable cardioverter-defibrillator
IDE = Investigational Device Exemption
IVCD = intraventricular conduction delay
LBBAP = left bundle branch area pacing
LBBB = left bundle branch block
LGE = late gadolinium enhancement
LOE = Level of Evidence
LV = left ventricular
LVAD = left ventricular assist device
LVEF = left ventricular ejection fraction
M = May Be Appropriate
MI = myocardial infarction
MMVT = monomorphic ventricular tachycardia
MRA = mineralocorticoid antagonist
NCDR = National Cardiovascular Data Registry
NSVT = nonsustained ventricular tachycardia
NYHA = New York Heart Association
PM = pacemaker
PMVT = polymorphic ventricular tachycardia
QOL = quality of life
R = Rarely Appropriate
RBBB = right bundle branch block
RV = right ventricular
S-ICD = subcutaneous implantable cardioverter-defibrillator
SCD = sudden cardiac death
SGLT2i = sodium-glucose cotransporter 2 inhibitor
SVT = supraventricular tachycardia
TV-ICD = transvenous implantable cardioverter-defibrillator
VAD = ventricular assist device
VF = ventricular fibrillation
VT = ventricular tachycardia

6. AUC RATINGS (BY CLINICAL SCENARIO)

The final AUC ratings are listed by clinical scenario in Tables 1.1 to 12.1 and reflect the median score of the 17 rating panel members. These scores have been labeled according to the categories of Appropriate/A (median score 7 to 9), May Be Appropriate/M (median score 4 to 6), or Rarely Appropriate/R (median score 1 to 3). The final score for each scenario is shown in parentheses next to the AUC rating of A, M, or R. Figures are included for many of the tables to highlight more frequently encountered or complex scenarios felt to be of particular importance by the writing group.

Before each table, additional considerations that went into construction of the clinical scenarios are discussed. Although the writing group attempted to be as comprehensive as possible, all clinical scenarios encountered in daily practice could not be included, but the more commonly encountered ones are described.

Clinical scenarios involving the initial implantation of ICDs were separated into primary and secondary prevention indications, as these represent unique patient populations. Modifying considerations such as type of heart disease, LVEF, NYHA functional class, or timing after MI or revascularization, were included for specific clinical scenarios when deemed appropriate by the writing group, based on the evidence and enrollment criteria in previous clinical trials, guideline recommendations, consensus

document recommendations, and/or clinical judgment based on practice experience with real-world populations.

Section 1: Secondary Prevention ICD

Assumptions and Considerations:

- These situations refer to recommendations where an ICD is being considered with an intent to *implant the device prior to hospital discharge.*
- It is assumed that an EP study was not performed unless otherwise specified.
- For the channelopathies, it is assumed that other guideline recommendations, such as refraining from exercise where appropriate, are being adhered to.

It is well established that patients who survive an out-of-hospital cardiac arrest unassociated with a transient or reversible cause or present with symptomatic sustained VT are at high risk for recurrent sustained ventricular arrhythmias and mortality. Randomized clinical trials have demonstrated the benefit of ICD therapy for the secondary prevention of SCD.[42-44]

A meta-analysis using individual patient data from the AVID (Antiarrhythmics Vs Implantable Defibrillator) study, the CASH (Cardiac Arrest Study Hamburg) study, and CIDS (Canadian Implantable Defibrillator Study) comparing the efficacy of ICD therapy vs amiodarone demonstrated a significant reduction in death from any cause with the ICD when compared with amiodarone (hazard ratio [HR]: 0.72; 95% CI: 0.60-0.87; $P = 0.006$).[45] This 28% reduction in the relative risk of death with the ICD was almost entirely due to the 50% reduction in risk of arrhythmic death. Patients who had an LVEF ≤35% derived significantly more benefit from ICD therapy than those with more preserved LV function. In addition, patients treated prior to the availability of nonthoracotomy ICDs derived significantly less benefit from ICD therapy than those treated with transvenous devices.[45] Although the evidence supporting ICD therapy for secondary prevention is based on randomized trials that were performed >20 years ago, more contemporary registries or

TABLE 1.1 CAD: Hemodynamically Unstable or Sustained VT, Polymorphic VT, or VF Associated With Acute (<48 Hours) MI (Newly Diagnosed, No Prior Assessment of LVEF, or Prior Normal LVEF)

Indication	Appropriate Use Score (1-9)		
Total Revascularization Completed After Cardiac Arrest			
LVEF	**≥50%**	**36%-49%**	**≤35%**
1. ■ Single episode of VF or polymorphic VT during acute (<48 hours) MI	R (2)	R (3)	M (4)
2. ■ Recurrent VF or polymorphic VT during acute (<48 hours) MI	R (3)	R (3)	M (5)
3. ■ Single episode of sustained monomorphic VT during acute (<48 hours) MI	R (2)	R (3)	M (4)
No Revascularization Indicated (ie, Nonobstructive CAD)			
LVEF	**≥50%**	**36%-49%**	**≤35%**
4. ■ Single episode of VF or polymorphic VT during acute (<48 hours) MI	R (2)	R (3)	M (4)
5. ■ Recurrent VF or polymorphic VT during acute (<48 hours) MI	R (3)	M (4)	M (6)
Obstructive CAD With Coronary Anatomy Not Amenable to Revascularization			
LVEF	**≥50%**	**36%-49%**	**≤35%**
6. ■ VF or polymorphic VT during acute (<48 hours) MI ■ No EPS done	M (5)	M (6)	A (7)

A = Appropriate; CAD = coronary artery disease; EPS = electrophysiological study with programmed stimulation to induce VT; LVEF = left ventricular ejection fraction; M = May Be Appropriate; MI = myocardial infarction; R = Rarely Appropriate; VF = ventricular fibrillation; VT = ventricular tachycardia.

TABLE 1.2 CAD: Hemodynamically Unstable or Sustained VT, Polymorphic VT, or VF <48 Hours (Acute) Post-Elective Revascularization

Indication	Appropriate Use Score (1-9)		
LVEF	**≥50%**	**36%-49%**	**≤35%**
7. ■ No evidence for acute coronary occlusion, restenosis, acute infarct, or other clearly reversible cause	M (6)	M (6)	A (7)

A = Appropriate; CAD = coronary artery disease; LVEF = left ventricular ejection fraction; M = May Be Appropriate; VF = ventricular fibrillation; VT = ventricular tachycardia.

TABLE 1.3 CAD: Hemodynamically Unstable or Sustained VT, Polymorphic VT, or VF (No Recent MI [≤40 Days] Prior to VF/VT and/or No Recent Revascularization [≤3 Months] Prior to VF/VT)

Indication	Appropriate Use Score (1-9)		
LVEF	**≥50%**	**36%-49%**	**≤35%**
8. ■ No identifiable transient and completely reversible causes ■ No need for revascularization identified by catheterization performed following VF/VT	A (8)	A (9)	A (9)
9. ■ Significant CAD present at catheterization performed following VF/VT, but coronary anatomy not amenable to revascularization ■ No revascularization performed	A (8)	A (9)	A (9)
10. ■ Significant CAD identified at catheterization performed following VF/VT ■ Complete revascularization performed after cardiac arrest	M (5)	M (6)	A (7)
11. ■ Significant CAD identified at catheterization performed following VF/VT ■ Incomplete revascularization performed after cardiac arrest	A (7)	A (8)	A (8)

A = Appropriate; CAD = coronary artery disease; LVEF = left ventricular ejection fraction; M = May Be Appropriate; MI = myocardial infarction; VF = ventricular fibrillation; VT = ventricular tachycardia.

TABLE 1.4 CAD: Hemodynamically Unstable or Sustained VT, Polymorphic VT, or VF During Exercise Testing Associated With Significant CAD

Indication	Appropriate Use Score (1-9)		
LVEF	**≥50%**	**36%-49%**	**≤35%**
12. ■ Significant CAD present at catheterization performed following VF/VT, but coronary anatomy not amenable to revascularization. No revascularization performed	A (8)	A (9)	A (9)
13. ■ Significant CAD identified at catheterization performed following VF/VT ■ Complete revascularization performed after cardiac arrest	M (5)	M (6)	A (7)
14. ■ Significant CAD identified at catheterization performed following VF/VT ■ Incomplete revascularization performed after cardiac arrest	A (7)	A (7)	A (8)

A = Appropriate; CAD = coronary artery disease; LVEF = left ventricular ejection fraction; M = May Be Appropriate; VF = ventricular fibrillation; VT = ventricular tachycardia.

observational studies in clinical practice support these findings.[46-48]

Based on results of randomized clinical trials, the "2017 AHA/ACC/HRS Guideline for Management of Patients With Ventricular Arrhythmias and the Prevention of Sudden Cardiac Death" gives a Class I recommendation for ICD therapy in patients with ischemic or nonischemic heart disease, who either survive sudden cardiac arrest due to VT/VF or experience hemodynamically unstable VT or stable sustained VT not due to reversible causes, if meaningful survival >1 year is expected.[4] In the European guidelines, ICD therapy for secondary prevention of SCD is recommended (Class I recommendation) in patients with documented VF or hemodynamically poorly tolerated VT in the absence of reversible causes or within 48 hours after MI who are receiving chronic optimal medical therapy and have a reasonable expectation of survival with a good functional status >1 year.[49]

In some patients who present with sustained ventricular arrhythmias, a transient or reversible cause, such as acute MI, electrolyte abnormalities, or proarrhythmia due to medication may be suggested as a potential etiology for cardiac arrest or sustained VT. While initial treatment

TABLE 1.5 No CAD: Hemodynamically Unstable or Sustained VT, Polymorphic VT, or VF

Indication*	Appropriate Use Score (1-9)		
LVEF	**≥50%**	**36%-49%**	**≤35%**
15. ■ Nonischemic dilated cardiomyopathy	A (8)	A (9)	A (9)
16. ■ VT/VF associated with cocaine substance use disorder	R (2)	M (4)	M (5)
Severe Valvular Disease VT/VF <48 Hours After Surgical Repair or Replacement of Aortic or Mitral Valve			
17. ■ No evidence of significant postoperative valvular dysfunction	M (5)	M (5)	M (6)
VF/Hemodynamically Unstable VT Associated With Other Structural Heart Disease			
18. ■ Myocardial sarcoidosis	A (9)		
19. ■ Myocarditis; not giant-cell myocarditis	M (6)		
20. ■ Giant-cell myocarditis	A (8)		
21. ■ Takotsubo cardiomyopathy (stress-induced cardiomyopathy, apical ballooning syndrome) ■ ≥48 hours of onset of symptoms	M (4)		

*No evidence of conduction disease requiring pacing.

A = Appropriate; CAD = coronary artery disease; LVEF = left ventricular ejection fraction; M = May Be Appropriate; R = Rarely Appropriate; VF = ventricular fibrillation; VT = ventricular tachycardia.

TABLE 1.6 Genetic Diseases With Sustained VT/VF*

Indication	Appropriate Use Score (1-9)
22. ■ Congenital long QT syndrome	A (9)
23. ■ Short QT syndrome	A (9)
24. ■ Catecholaminergic polymorphic VT	A (9)
25. ■ Brugada syndrome	A (9)
26. ■ ARVC with successful ablation of all inducible monomorphic VTs	A (9)
27. ■ ARVC with unsuccessful attempt to ablate an inducible VT	A (9)
28. ■ ARVC without attempted ablation	A (9)
29. ■ Hypertrophic cardiomyopathy	A (9)

*Patients with genetic diseases are assumed to have normal LV and RV function, unless otherwise specified.

A = Appropriate; ARVC = arrhythmogenic right ventricular cardiomyopathy; VF = ventricular fibrillation; VT = ventricular tachycardia.

TABLE 1.7 No Structural Heart Disease (LVEF ≥50%) or Known Genetic Causes of Sustained VT/VF

Indication	Appropriate Use Score (1-9)
Pharmacologically Induced Sustained VT/VF	
30. ■ Non-TdP VT/VF in the setting of antiarrhythmic drug use	R (3)
31. ■ Drug-induced TdP	R (2)
Idiopathic VF With Normal Ventricular Function	
32. ■ No family history of sudden cardiac death	A (8)
33. ■ First-degree relative with sudden cardiac death	A (9)
Sustained VT/VF With Electrolyte Abnormalities	
34. ■ Hypokalemia	M (4)
Other Causes	
35. ■ Bradycardia-dependent VF/TdP	M (5)
36. ■ WPW syndrome with VT/VF ■ Pathway successfully ablated ■ Structurally normal heart	R (2)

A = Appropriate; LVEF = left ventricular ejection fraction; M = May Be Appropriate; R = Rarely Appropriate; TdP = torsades de pointes ventricular tachycardia; VF = ventricular fibrillation; VT = ventricular tachycardia; WPW = Wolff-Parkinson-White.

TABLE 1.8.1 Syncope in Patients Without Structural Heart Disease

	Indication	Appropriate Use Score (1-9)
	Unexplained Syncope With No Structural Heart Disease or Genetically Transmitted Ventricular Arrhythmias	
37.	■ Normal ECG and structurally normal heart ■ Family history of sudden death	R (3)
38.	■ Normal ECG and structurally normal heart ■ No known family history of sudden death	R (1)
	Unexplained Syncope in a Patient With RV or LV Outflow Tract Ventricular Tachycardia (Idiopathic VT) With Normal LV and RV Function and Anatomy	
39.	■ Documented sustained monomorphic VT (LBBB/inferior axis) at the time of syncope ■ Ablation not yet attempted	R (3)
40.	■ Documented history of sustained monomorphic VT (LBBB/inferior axis) but not recorded at the time of syncope ■ Ablation not yet attempted	R (3)
41.	■ Documented sustained monomorphic VT (LBBB/inferior axis) at the time of syncope ■ Ablation successful	R (2)
	Unexplained Syncope in a Patient With Long QT Syndrome	
42.	■ While on treatment with beta-blockers	A (7)
43.	■ Not being treated with beta-blockers	M (6)
	Unexplained Syncope in a Patient With Brugada ECG Pattern	
44.	■ No EPS performed	A (7)
45.	■ EPS performed ■ No ventricular arrhythmias induced	A (7)
46.	■ EPS performed ■ Sustained VT/VF induced	A (9)
	Unexplained Syncope in a Patient With Catecholaminergic Polymorphic VT*	
47.	■ While on treatment with beta-blockers	A (7)
48.	■ Not being treated with beta-blockers	M (5)
49.	■ Not being treated with beta-blockers or flecainide	M (5)

*It is assumed that appropriate exercise recommendations are being followed.

A = Appropriate; ECG = electrocardiogram; EPS = electrophysiological study; LBBB = left bundle branch block; LV = left ventricular; M = May Be Appropriate; R = Rarely Appropriate; RV = right ventricular; VF = ventricular fibrillation; VT = ventricular tachycardia.

TABLE 1.8.2 Syncope in Patients With CAD

	Indication	Appropriate Use Score (1-9)
	Unexplained Syncope With Coronary Heart Disease and No Acute MI LVEF ≥50%	
50.	■ EPS and noninvasive investigations failed to define a cause of syncope ■ No prior MI ■ Nonobstructive CAD; revascularization not indicated	R (2)
51.	■ EPS and noninvasive investigations failed to define a cause of syncope ■ No prior MI ■ Obstructive CAD; not amenable to revascularization	R (3)
	Unexplained Syncope With Prior MI and No Acute MI LVEF 36%-49%	
52.	■ EPS failed to define a cause of syncope ■ Prior MI ■ Nonobstructive CAD; revascularization not indicated	M (4)
53.	■ EPS failed to define a cause of syncope ■ Prior MI ■ Obstructive CAD; not amenable to revascularization	M (6)
54.	■ EPS revealed inducible sustained VT/VF ■ Prior MI	A (8)
	Unexplained Syncope With Prior MI and No Acute MI LVEF ≤35%	
55.	■ EPS not performed	A (8)
56.	■ Inducible VT/VF at EPS	A (9)
57.	■ Not inducible at EPS	A (8)

A = Appropriate; CAD = coronary artery disease; EPS = electrophysiological study; LVEF = left ventricular ejection fraction; M = May Be Appropriate; MI = myocardial infarction; R = Rarely Appropriate; VF = ventricular fibrillation; VT = ventricular tachycardia.

should be directed at the underlying disorder and a thorough evaluation is warranted, it is often difficult to exclude primary arrhythmic etiologies. In the AVID trial, patients identified as having "potentially transient or potentially correctable" causes of VT/VF were not eligible for randomization and were followed in a registry[50]; however, these patients remained at high mortality risk.[50]

In the 2017 AHA/ACC/HRS guidelines, a Class I recommendation for ICD therapy is also given for patients with ischemic heart disease and unexplained syncope who have inducible sustained monomorphic ventricular tachycardia (MMVT) at EP study, if meaningful survival of >1 year is expected.[4] For patients with nonischemic CM who experience syncope presumed to be due to ventricular arrhythmia, an ICD can be beneficial if meaningful survival >1 year is expected (Class IIa recommendation).[4]

ICD indications for secondary prevention of SCD include appropriate use scenarios where patients present with sustained VT, VF, or syncope felt to have an arrhythmic origin in high-risk patients (described in Tables 1.1 to 1.9, Figures 1 to 8). In this appropriate use document, secondary prevention scenarios are modified by factors such as type of heart disease, timing post-MI, need for revascularization, hemodynamic stability, or findings at EP study.

Section 1 Results and Discussion

Secondary prevention ICD indications include patients presenting with sustained VT, VF, or syncope with high-risk characteristics. Clinical scenarios in this document include a variety of accompanying acute and chronic conditions that could modify consideration of the risk of subsequent recurrence of sustained ventricular arrhythmias or SCD.

TABLE 1.8.3 Syncope in Patients With Nonischemic Structural Heart Disease

Indication	Appropriate Use Score (1-9)		
Unexplained Syncope in a Patient With Left Ventricular Hypertrophy Without Criteria for Hypertrophic Cardiomyopathy			
LVEF	**≥50%***	**36%-49%**	**≤35%**
58. ■ Left ventricular hypertrophy/ hypertensive heart disease	R (2)	M (4)	A (7)
Unexplained Syncope in a Patient With Nonischemic Cardiomyopathy			
LVEF	**≥50%***	**36%-49%**	**≤35%**
59. ■ Nonischemic dilated cardiomyopathy	M (4)	M (6)	A (8)
60. ■ Left ventricular noncompaction	M (6)	A (7)	A (8)
61. ■ Cardiac amyloidosis, with good functional status (NYHA functional class I-II)	M (4)	M (5)	M (6)
62. ■ Hypertrophic cardiomyopathy		A (8)	
63. ■ Tetralogy of Fallot with prior corrective surgery		A (7)	
Unexplained Syncope in a Patient with Arrhythmogenic Right Ventricular Cardiomyopathy			
64. ■ No EPS performed		A (7)	
65. ■ No inducible VT/VF at EPS		A (7)	
66. ■ Inducible VT/VF at EPS ■ All inducible VTs successfully ablated		A (7)	
67. ■ Inducible VT/VF at EPS ■ Ablation unsuccessful		A (8)	

*LVEF preserved on medical therapy.

A = Appropriate; EPS = electrophysiological study; LVEF = left ventricular ejection fraction; M = May Be Appropriate; NYHA = New York Heart Association; R = Rarely Appropriate; VF = ventricular fibrillation; VT = ventricular tachycardia.

TABLE 1.9 Sustained Hemodynamically Stable Monomorphic VT Associated With Structural Heart Disease

Indication	Appropriate Use Score (1-9)		
LVEF	**≥50%***	**36%-49%**	**≤35%**
68. ■ CAD and prior MI	A (7)	A (7)	A (9)
69. ■ CAD and prior MI ■ All inducible VTs successfully ablated	M (6)	M (6)	A (9)
70. ■ CAD and prior MI ■ Troponin elevation thought to be secondary to VT ■ All inducible VTs successfully ablated	M (6)	A (7)	A (9)
71. ■ Nonischemic dilated cardiomyopathy	A (7)	A (7)	A (9)
72. ■ Nonischemic dilated cardiomyopathy ■ All inducible VTs successfully ablated	M (6)	A (7)	A (8)
73. ■ Bundle branch re-entry successfully ablated in a patient with nonischemic cardiomyopathy	R (3)	M (5)	A (7)

*LVEF preserved on medical therapy.

A = Appropriate; CAD = coronary artery disease; LVEF = left ventricular ejection fraction; M = May Be Appropriate; MI = myocardial infarction; R = Rarely Appropriate; VF = ventricular fibrillation; VT = ventricular tachycardia.

VF or Sustained Polymorphic VT

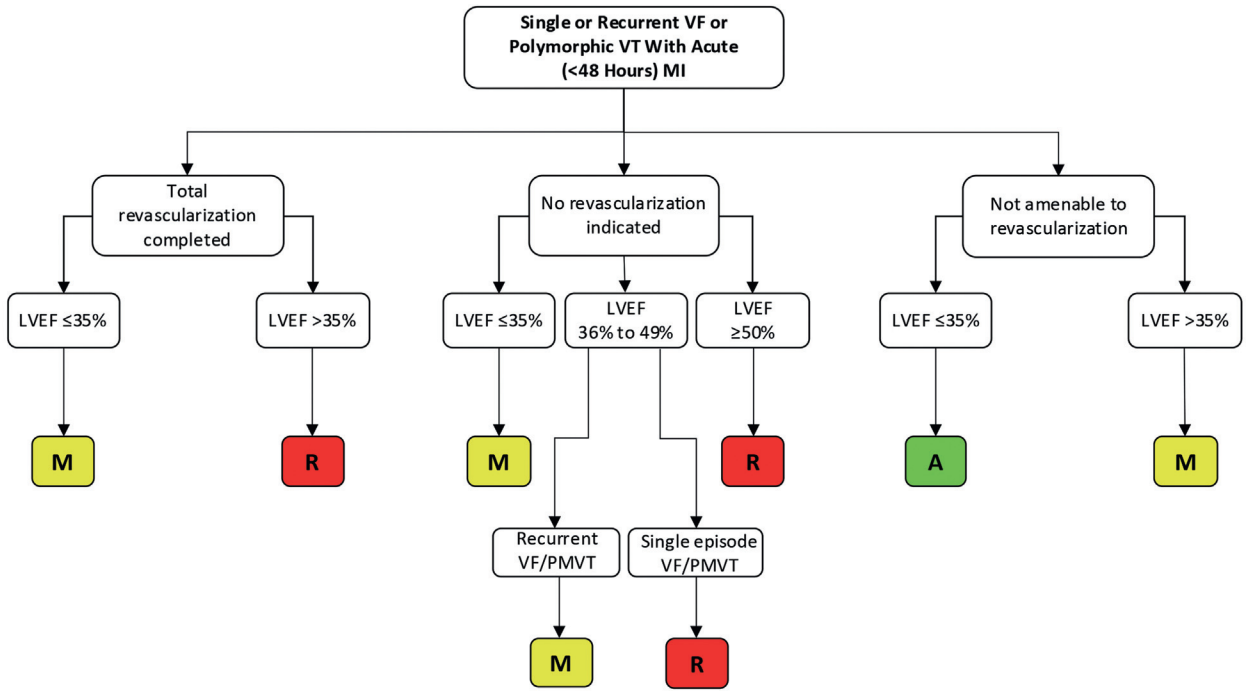
Scenarios in which patients presented with VF or sustained polymorphic ventricular tachycardia (PMVT) in the setting of CAD, modified by timing post-MI and timing postrevascularization, or occurring in the setting of exercise testing are described in Tables 1.1 to 1.4 (Figures 1 and 2). Sustained MMVT was excluded from these early post-MI scenarios because a more uniform tachycardia typically represents a stable substrate that is often related to re-entry, and the risk of arrhythmia recurrence may be higher than that seen for patients with PMVT/VF. ICD implantation was considered Rarely Appropriate for most of these scenarios where VF or PMVT occurred in the setting of acute (<48 hours) MI, particularly in the setting of preserved or only mild to moderately reduced LV systolic function (Table 1.1, Figure 1). This is consistent with clinical evidence and guidelines stating that ICD implantation should not be recommended for arrhythmias considered "completely reversible"; however, indications were rated as May Be Appropriate if LVEF was ≤35%. These indications may include patients with LV dysfunction that could have been pre-existing, because the scenarios did not include mention of any prior assessment of LVEF, or there may be little chance for recovery of LV function in the absence of revascularization in some scenarios. ICD implantation was rated as Appropriate for VF or PMVT in the setting of obstructive CAD with coronary anatomy not amenable to revascularization if LVEF ≤35%. The presence of obstructive coronary disease that is not amenable to revascularization could place the patient at continued risk for recurrent arrhythmias and, therefore, may not qualify as a "completely reversible" cause.

Sustained VT/VF occurring in the setting of nonischemic heart disease, including genetic diseases, infiltrative CM, or myocarditis, as well as no detectable structural heart disease are described in Tables 1.5 to 1.7 (Figures 3 and 4). Several of these scenarios are not specifically addressed in the guidelines or clinical trials and may represent a relatively small percentage of patients undergoing ICD implantation. Therefore, clinical judgment based on review of limited evidence is often required when making these decisions.

Syncope

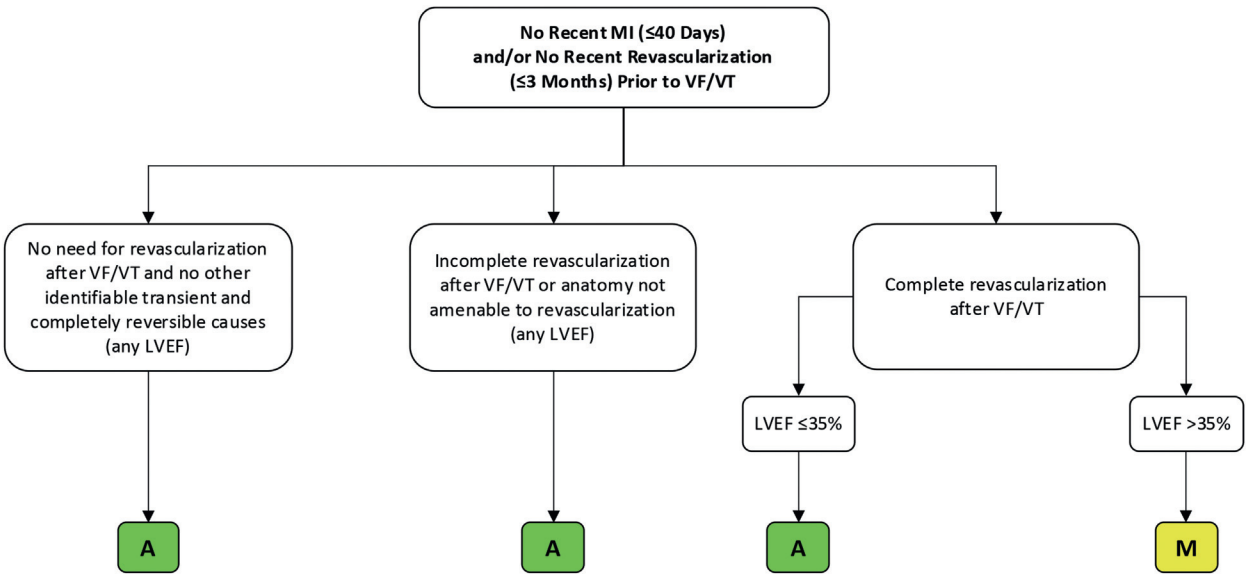
Scenarios involving syncope included those with and without underlying structural heart disease or concomitant CAD (Tables 1.8.1 to 1.8.3, Figure 5). In patients without structural heart disease, ICD implantation was rated Appropriate when occurring in the setting of long QT syndrome while on treatment with beta-blockers, a Brugada ECG pattern regardless of findings at invasive electrophysiological testing, and catecholaminergic PMVT while on treatment with beta-blockers (Table 1.8.1, Figure 5). In contrast, ICD implantation was rated as

FIGURE 1 **Summary of Table 1.1, Secondary Prevention: CAD—Hemodynamically Unstable or Sustained VT, PMVT, or VF Associated With Acute (<48 Hours) MI (Newly Diagnosed, No Prior Assessment of LVEF, or Prior Normal LVEF)**



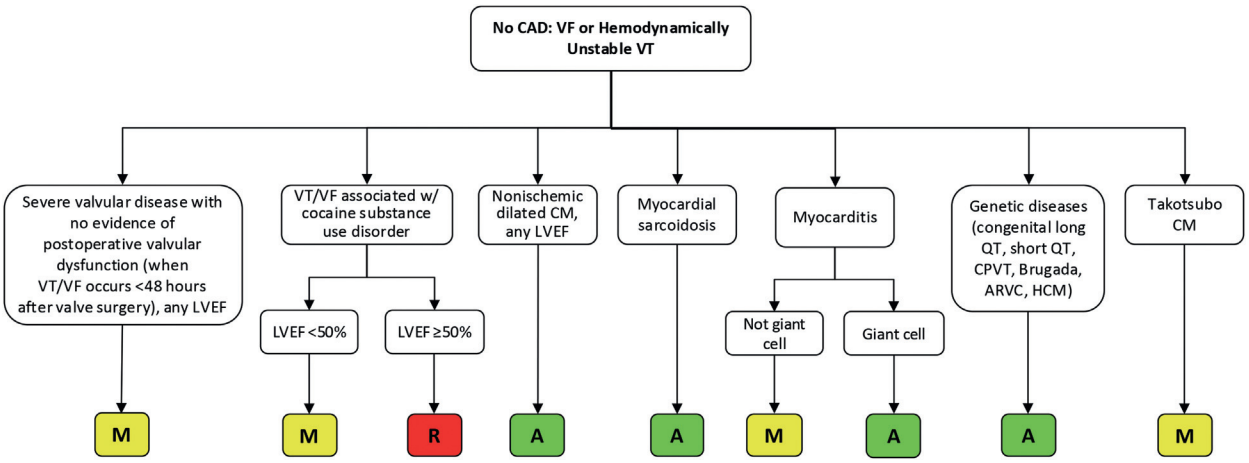
A = Appropriate; CAD = coronary artery disease; LVEF = left ventricular ejection fraction; M = May Be Appropriate; MI = myocardial infarction; PMVT = polymorphic ventricular tachycardia; R = Rarely Appropriate; VF = ventricular fibrillation; VT = ventricular tachycardia.

FIGURE 2 **Summary of Table 1.3, Secondary Prevention: CAD—Hemodynamically Unstable or Sustained VT, Polymorphic VT, or VF (No Recent MI [≤40 Days] Prior to VF/VT and/or No Recent Revascularization [≤3 Months] Prior to VF/VT)**



A = Appropriate; CAD = coronary artery disease; LVEF = left ventricular ejection fraction; M = May Be Appropriate; MI = myocardial infarction; VF = ventricular fibrillation; VT = ventricular tachycardia.

FIGURE 3 **Summary of Tables 1.5 and 1.6, Secondary Prevention: VF or Hemodynamically Unstable VT—No CAD With Structural Heart Disease or Genetic Disorders**

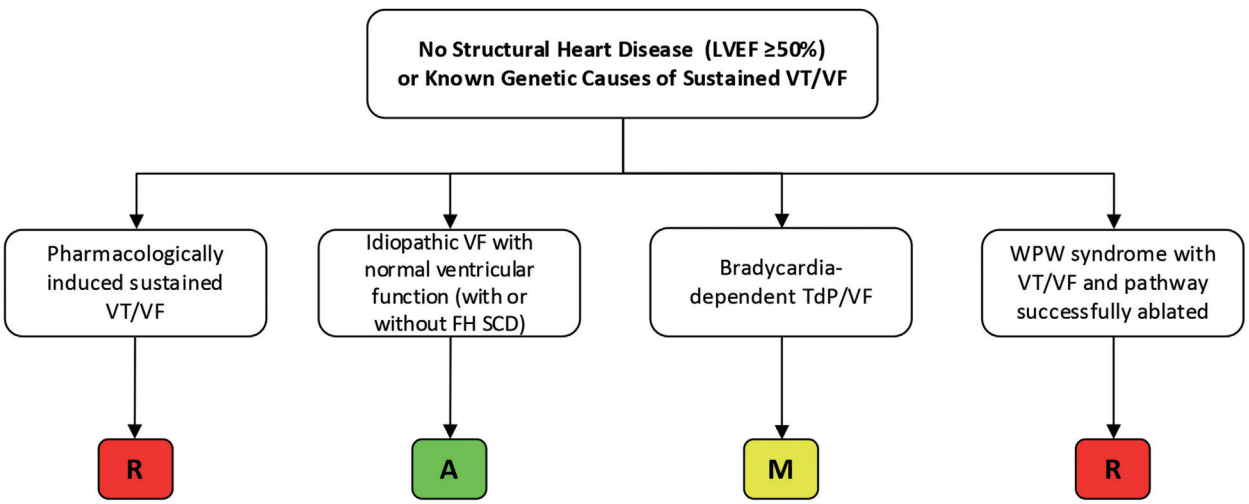


A = Appropriate; ARVC = arrhythmogenic right ventricular cardiomyopathy; CAD = coronary artery disease; CM = cardiomyopathy; CPVT = catecholaminergic polymorphic ventricular tachycardia; HCM = hypertrophic cardiomyopathy; LVEF = left ventricular ejection fraction; M = May Be Appropriate; R = Rarely Appropriate; VF = ventricular fibrillation; VT = ventricular tachycardia.

Rarely Appropriate in patients with unexplained syncope who have a normal heart and normal ECG and do not have a genetic condition associated with sudden death, or when syncope occurs in patients with normal LV function and idiopathic VT (including RV outflow tract VT or idiopathic LV VT) regardless of whether ablation was performed. The latter is consistent with the good prognosis of patients with idiopathic VT.

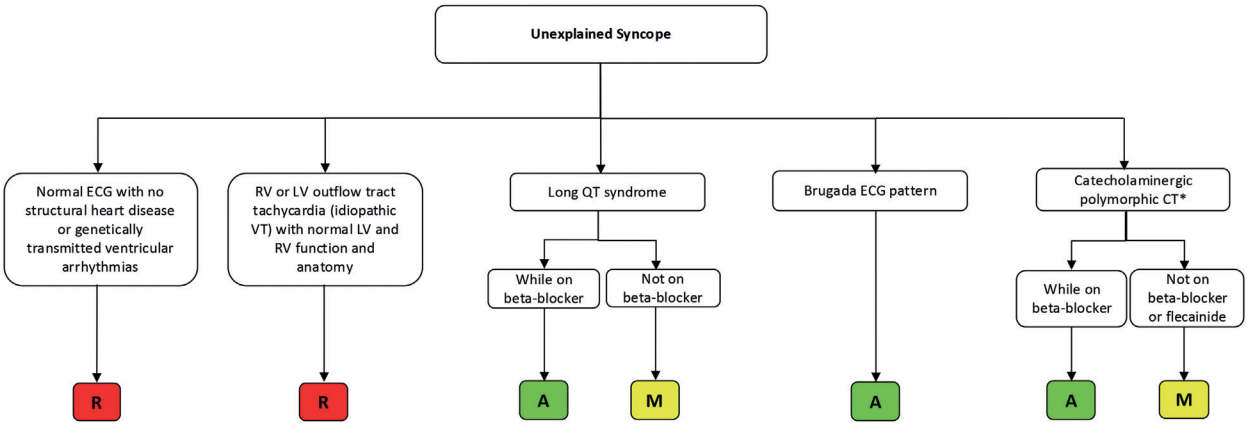
In patients with syncope in the setting of CAD, scenarios were modified by LVEF (Table 1.8.2, Figure 6). In patients with unexplained syncope, prior MI, and an LVEF ≤35%, ICD implantation was considered

FIGURE 4 **Summary of Table 1.7, Secondary Prevention: No Structural Heart Disease (LVEF ≥50%) or Known Genetic Causes of Sustained VT/VF**



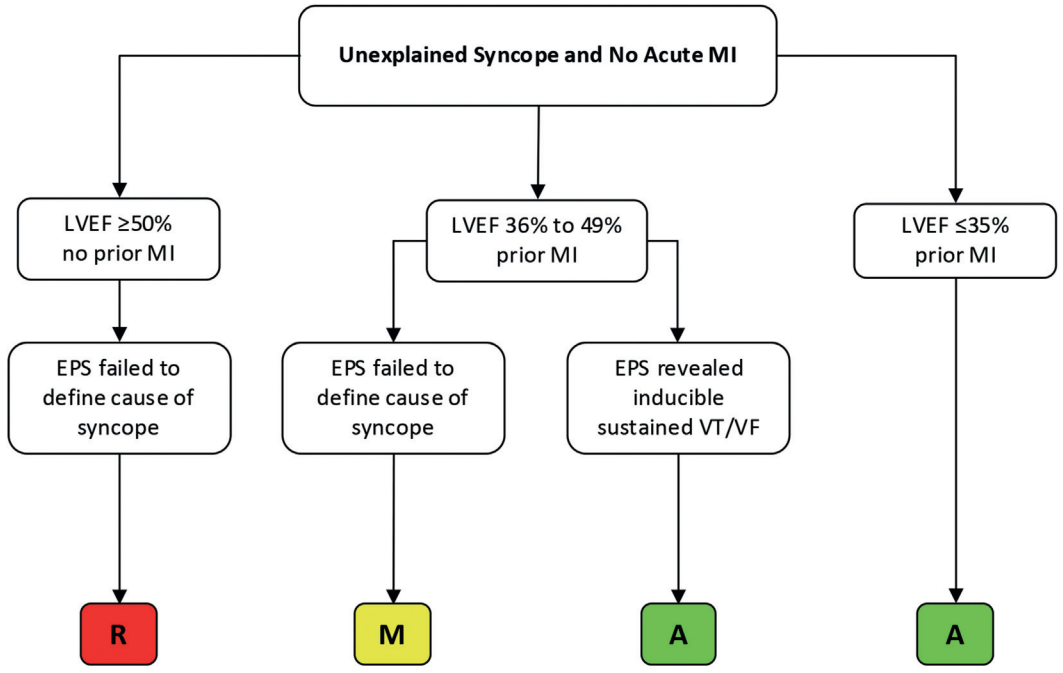
A = Appropriate; FH = family history; LVEF = left ventricular ejection fraction; M = May Be Appropriate; R = Rarely Appropriate; SCD = sudden cardiac death; TdP = torsades de pointes ventricular tachycardia; VF = ventricular fibrillation; VT = ventricular tachycardia; WPW = Wolff-Parkinson-White.

FIGURE 5 **Summary of Table 1.8.1, Secondary Prevention: Syncope in Patients Without Structural Heart Disease**



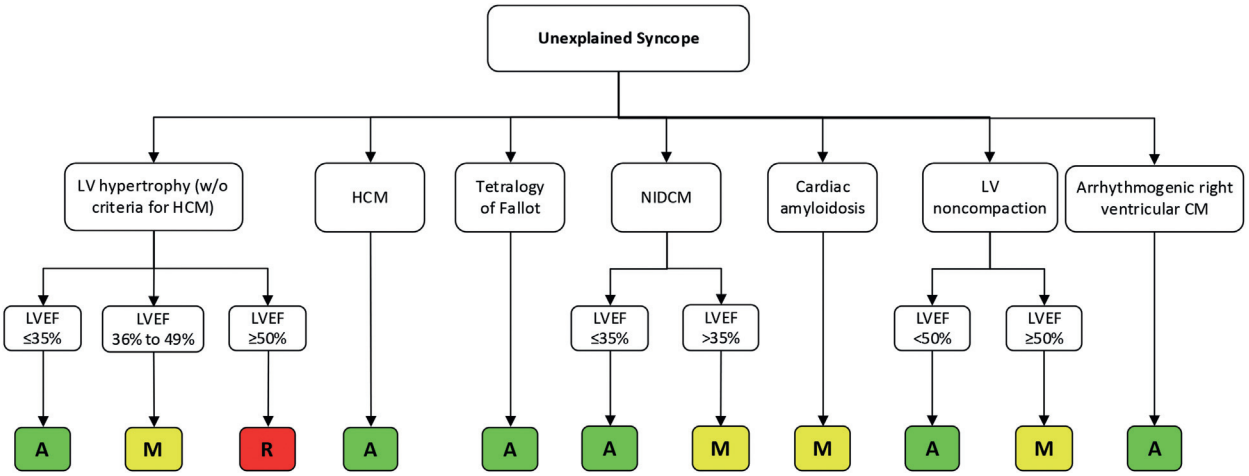
*It is assumed that appropriate exercise recommendations are being followed. A = Appropriate; ECG = electrocardiogram; LV = left ventricular; M = May Be Appropriate; R = Rarely Appropriate; RV = right ventricular; VT = ventricular tachycardia.

FIGURE 6 **Summary of Table 1.8.2, Secondary Prevention: Syncope in Patients With CAD**



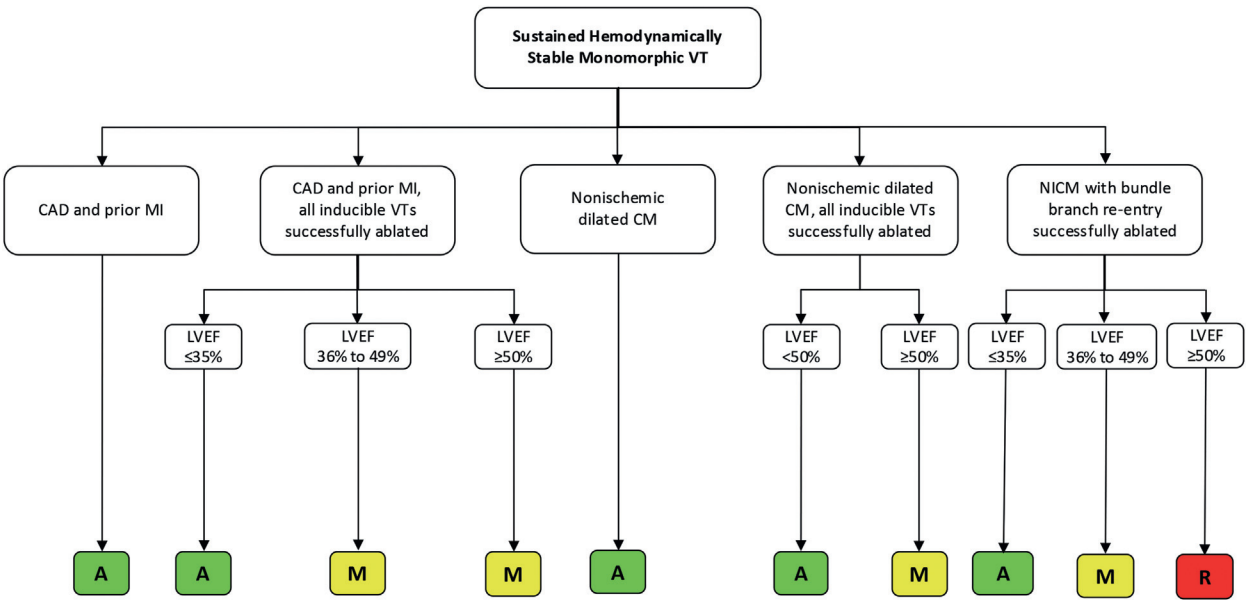
A = Appropriate; CAD = coronary artery disease; EPS = electrophysiological study; LVEF = left ventricular ejection fraction; M = May Be Appropriate; MI = myocardial infarction; R = Rarely Appropriate; VF = ventricular fibrillation; VT = ventricular tachycardia.

FIGURE 7 **Summary of Table 1.8.3, Secondary Prevention: Syncope in Patients With Nonischemic Structural Heart Disease**



A = Appropriate; CM = cardiomyopathy; HCM = hypertrophic cardiomyopathy; LV = left ventricular; LVEF = left ventricular ejection fraction; M = May Be Appropriate; NIDCM = nonischemic dilated cardiomyopathy; R = Rarely Appropriate.

FIGURE 8 **Summary of Table 1.9, Secondary Prevention: Sustained Hemodynamically Stable Monomorphic VT Associated With Structural Heart Disease**



A = Appropriate; CAD = coronary artery disease; LVEF = left ventricular ejection fraction; MI = myocardial infarction; NICM = nonischemic cardiomyopathy; VF = ventricular fibrillation; VT = ventricular tachycardia.

Appropriate regardless of the findings of the EP study. In the setting of a mildly reduced LVEF (36%- 49%) and prior MI, ICD implantation was considered Appropriate only if EP study revealed inducible sustained VT or VF, but was rated as May Be Appropriate if the EP study failed to define a cause, regardless of revascularization status.

In patients with nonischemic structural heart disease and syncope, scenarios were modified by type of heart disease, LVEF, and/or EP study status (Table 1.8.3, Figure 7). For example, in patients with arrhythmogenic RV CM, ICD implantation was considered Appropriate regardless of EP study or ablation status. In patients with nonischemic dilated CM and syncope, ICD implantation was considered Appropriate if LVEF ≤35% and May Be Appropriate for EF >35%.

Sustained Hemodynamically Tolerated MMVT

Hemodynamically tolerated sustained MMVT in the setting of structural heart disease was considered separately from hemodynamically unstable VT or VF, given the potential differences in arrhythmia substrate as well as the response of VT to catheter ablation. When occurring in the setting of LVEF ≤35%, regardless of the underlying disease process (ie, ischemic or nonischemic heart disease) or history of VT ablation, ICD implantation was considered Appropriate (Table 1.9, Figure 8).

Section 2: Primary Prevention ICD

2.1. CAD

Assumptions and Considerations

In the absence of sustained VT/VF or syncope, primary prevention ICD implantation may be considered in a variety of scenarios to reduce mortality related to potentially life threatening sustained ventricular arrhythmias. Specific time periods for implantation of primary prevention ICDs (ie, 40 days after an acute MI, 3 months after revascularization, and 3 months after initial diagnosis of a CM) are described. These time periods were selected for this appropriate use document based on prior clinical trials, guideline documents,[4] consensus statements[7] or contemporary practice. A "waiting period" following MI is supported by the IRIS (Immediate Risk-Stratification Improves Survival) trial and DINAMIT (Defibrillator IN Acute Myocardial Infarction Trial), which demonstrated no overall survival benefit of ICD therapy when devices were implanted very early (within 30 or 40 days) following MI.[41,51,52] Scenarios in this section are also modified by LVEF, NYHA functional class, timing post-MI, and/or duration of medical therapy (Tables 2.1.1. to 2.1.6, Figures 9 and 10).

Timing Post-MI or Revascularization and EP Testing

Initial primary prevention ICD trials utilized EP testing in risk stratification. Many of the scenarios in Tables 2.1.1 to 2.1.4 consider some of the shorter time periods post-MI where limited trial data are available. The definition for MI has evolved in recent years.[37,38,53] For contemporary practice, the diagnosis of MI should be made according to the most recent statement, and future trials should precisely define MI and other diagnoses critical to major entry criteria. A lack of mortality benefit from the ICD was seen in DINAMIT,[51] and factors associated with

TABLE 2.1.1 Post-Acute MI (≤40 Days) LVEF ≤30%

	Indication	Appropriate Use Score (1-9)
Revascularization After Acute MI		
74.	■ No NSVT	R (2)
75.	■ Asymptomatic NSVT (≥4 days post-MI) ■ No EPS performed	R (3)
76.	■ Asymptomatic NSVT (≥4 days post-MI) ■ EPS with inducible sustained VT (EPS performed after revascularization, within 40 days of MI)	A (7)
77.	■ Asymptomatic NSVT (≥4 days post-MI) ■ EPS without inducible VT (EPS performed after revascularization, within 40 days after MI)	R (3)
78.	■ Asymptomatic NSVT (<4 days post-MI)	R (3)
Not Revascularized Obstructive CAD With Coronary Anatomy Not Amenable to Revascularization		
79.	■ No NSVT	R (2)
80.	■ Asymptomatic NSVT (≥4 days post-MI) ■ No EPS performed	M (4)
81.	■ Asymptomatic NSVT (≥4 days post-MI) ■ EPS with inducible sustained VT (EPS performed within 40 days of MI)	A (8)
82.	■ Asymptomatic NSVT (≥4 days post-MI) ■ EPS without inducible VT (EPS performed within 40 days of MI)	M (4)
83.	■ Asymptomatic NSVT (<4 days post-MI)	R (3)

A = Appropriate; CAD = coronary artery disease; EPS = electrophysiological study; LVEF = left ventricular ejection fraction; M = May Be Appropriate; MI = myocardial infarction; NSVT = nonsustained ventricular tachycardia; R = Rarely Appropriate; VT = ventricular tachycardia.

TABLE 2.1.2 Post-Acute MI (≤40 Days) LVEF 31% to 40%

	Indication	Appropriate Use Score (1-9)
Revascularized for Acute MI		
84.	■ No NSVT	R (2)
85.	■ Asymptomatic NSVT (≥4 days post-MI) ■ No EPS performed	R (3)
86.	■ Asymptomatic NSVT (≥4 days post-MI) ■ EPS with inducible sustained VT (EPS performed after revascularization, within 40 days of MI)	A (7)
87.	■ Asymptomatic NSVT (≥4 days post-MI) ■ EPS without inducible VT (EPS performed after revascularization, within 40 days of MI)	R (3)
88.	■ Asymptomatic NSVT (<4 days post-MI)	R (3)

A = Appropriate; EPS = electrophysiological study; LVEF = left ventricular ejection fraction; MI = myocardial infarction; NSVT = nonsustained ventricular tachycardia; R = Rarely Appropriate; VT = ventricular tachycardia.

TABLE 2.1.3 Post-Acute MI (≤40 Days) and Pre-Existing Chronic Cardiomyopathy (≥3 Months)

Indication		Appropriate Use Score (1-9)
89.	■ LVEF ≤30% due to old infarction ■ NYHA functional class I	A (7)
90.	■ LVEF ≤35% due to old infarction ■ NYHA functional class II-III	A (8)
91.	■ LVEF ≤35% due to nonischemic causes ■ NYHA functional class II-III	A (8)

A = Appropriate; LVEF = left ventricular ejection fraction; MI = myocardial infarction; NYHA = New York Heart Association.

arrhythmia requiring ICD therapy were also associated with a high risk of nonsudden death, negating the benefit of ICDs very early post-MI.[51] MUSTT (Multicenter Unsustained Tachycardia Trial) enrolled patients with CAD, LVEF ≤40%, and asymptomatic, nonsustained VT.[54] The qualifying arrhythmia had to have occurred ≤6 months before enrollment, and ≥4 days after the most recent MI or revascularization procedure. The trial showed that EP-guided therapy with ICDs, but not with antiarrhythmic drugs, reduced the risk of sudden death; however, >80% of randomized patients had experienced their most recent MI >1 month before enrollment. Thus, because few patients were enrolled in the first month post-MI, the utility of EP study in that period is uncertain.

These scenarios are also modified by the presence or absence of revascularization. To qualify for enrollment, MADIT II (Multicenter Automatic Defibrillator Implantation Trial II) required a waiting period of ≥3 months following coronary revascularization.[55] In contrast, patients were eligible for enrollment in MUSTT ≥4 days following revascularization, and 56% of patients enrolled in this trial underwent prior coronary artery bypass graft (CABG) surgery at some point in time[54]; however, post hoc analysis of MUSTT revealed that the occurrence of postoperative NSVT, especially within 10 days after CABG, portends a far better outcome than when it occurs in nonpostoperative settings.[56] As there are limited data related to EP testing very early following revascularization procedures, and available data suggest that NSVT in this

TABLE 2.1.4 Post-MI (≤40 Days) and Need for Guideline-Directed Pacemaker Therapy Post-MI (eg, SSS, CHB, or Other Indications for Permanent Pacemaker)

Indication		Appropriate Use Score (1-9)
92.	■ LVEF ≤35%	A (7)
93.	■ LVEF 36%-40%	M (6)

A = Appropriate; CHB = complete heart block; LVEF = left ventricular ejection fraction; M = May Be Appropriate; MI = myocardial infarction; SSS = sick sinus syndrome.

TABLE 2.1.5 Post-MI (>40 Days) With Ischemic Cardiomyopathy

Indication		Appropriate Use Score (1-9)	
No Recent PCI or CABG (≤3 Months)			
NYHA Functional Class		**I**	**II-III**
94.	■ LVEF ≤30%	A (8)	A (9)
95.	■ LVEF 31%-35%	A (7)	A (9)
96.	■ LVEF 36%-40% ■ Asymptomatic NSVT ■ No EPS	M (4)	M (4)
97.	■ LVEF 36%-40% ■ Asymptomatic NSVT ■ EPS without inducible VT/VF	R (3)	M (4)
98.	■ LVEF 36%-40% ■ Asymptomatic NSVT ■ EPS with inducible sustained VT/VF	A (7)	A (8)
Recent PCI or CABG (≤3 Months)		**Appropriate Use Score**	
99.	■ No known pre-existing cardiomyopathy ■ LVEF ≤35%	M (4)	
100.	■ Pre-existing documented cardiomyopathy ■ LVEF ≤35% on guideline-directed medical therapy for ≥3 months prior to PCI/CABG	A (7)	
101.	■ LVEF ≤35% ■ Need for PPM postrevascularization (eg, SSS, CHB, or other guideline-directed indications for PPM)	A (8)	
102.	■ LVEF 36%-40% ■ Need for PPM postrevascularization (eg, SSS, CHB, or other guideline-directed indications for PPM)	M (6)	

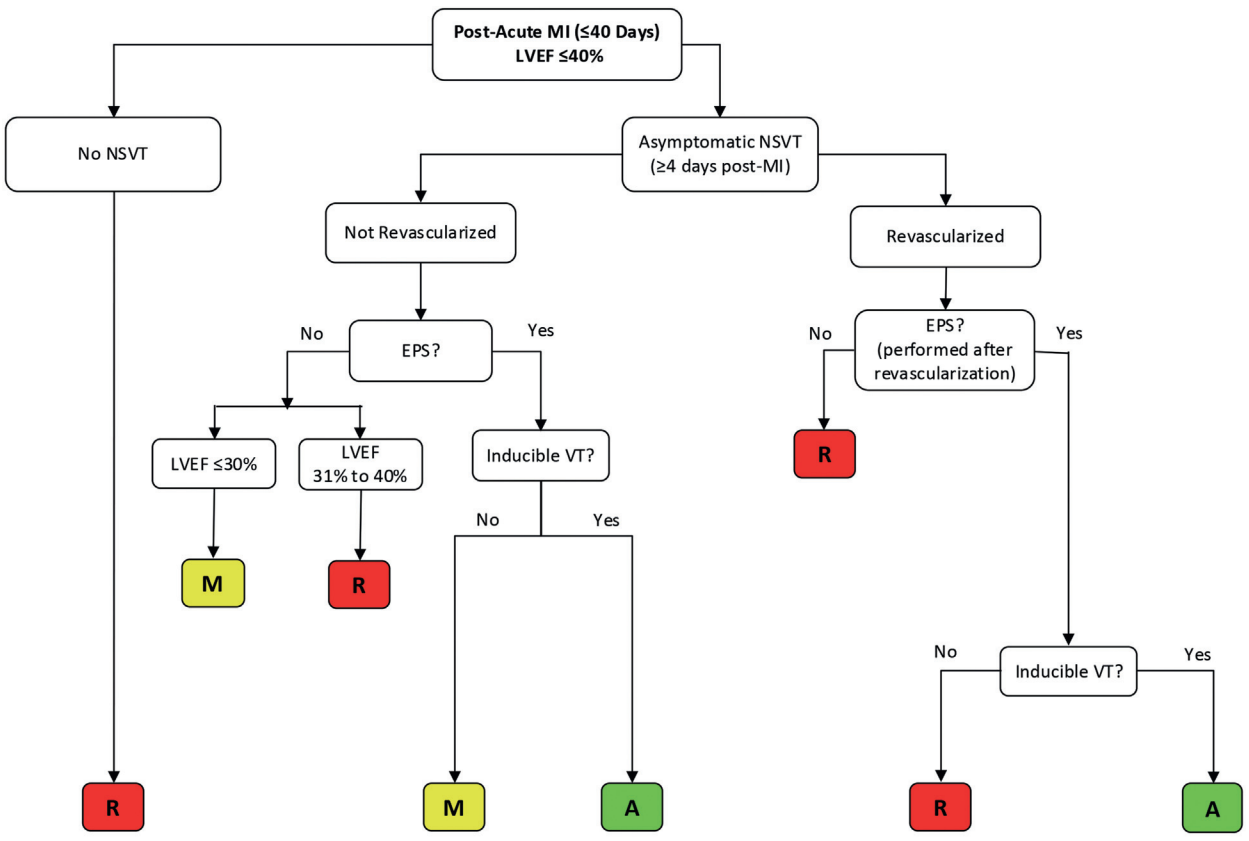
A = Appropriate; CABG = coronary artery bypass graft surgery; CHB = complete heart block; EPS = electrophysiological study; LVEF = left ventricular ejection fraction; M = May Be Appropriate; MI = myocardial infarction; NYHA = New York Heart Association; NSVT = nonsustained ventricular tachycardia; PCI = percutaneous coronary intervention; PPM = permanent pacemaker; R = Rarely Appropriate; SSS = sick sinus syndrome; VF = ventricular fibrillation; VT = ventricular tachycardia.

TABLE 2.1.6 Duration of Guideline-Directed Medical Therapy (<3 Months vs ≥3 Months) for Ischemic Cardiomyopathy Without Recent MI (Revascularization Not Indicated)

Indication		Appropriate Use Score (1-9)
103.	■ LVEF ≤35% ■ On guideline-directed medical therapy for <3 months	M (5)
104.	■ LVEF ≤35% ■ On guideline-directed medical therapy <3 months ■ NSVT ■ EPS *with* inducible sustained VT	A (8)
105.	■ LVEF ≤35% ■ On guideline-directed medical therapy <3 months ■ NSVT ■ EPS *without* inducible sustained VT	M (4)
106.	■ LVEF ≤35% ■ On guideline-directed medical therapy ≥3 months	A (9)

A = Appropriate; EP = electrophysiological study; LVEF = left ventricular ejection fraction; M = May Be Appropriate; MI = myocardial infarction; NSVT = nonsustained ventricular tachycardia; VT = ventricular tachycardia.

FIGURE 9 Summary of Tables 2.1.1 and 2.1.2, Primary Prevention, CAD



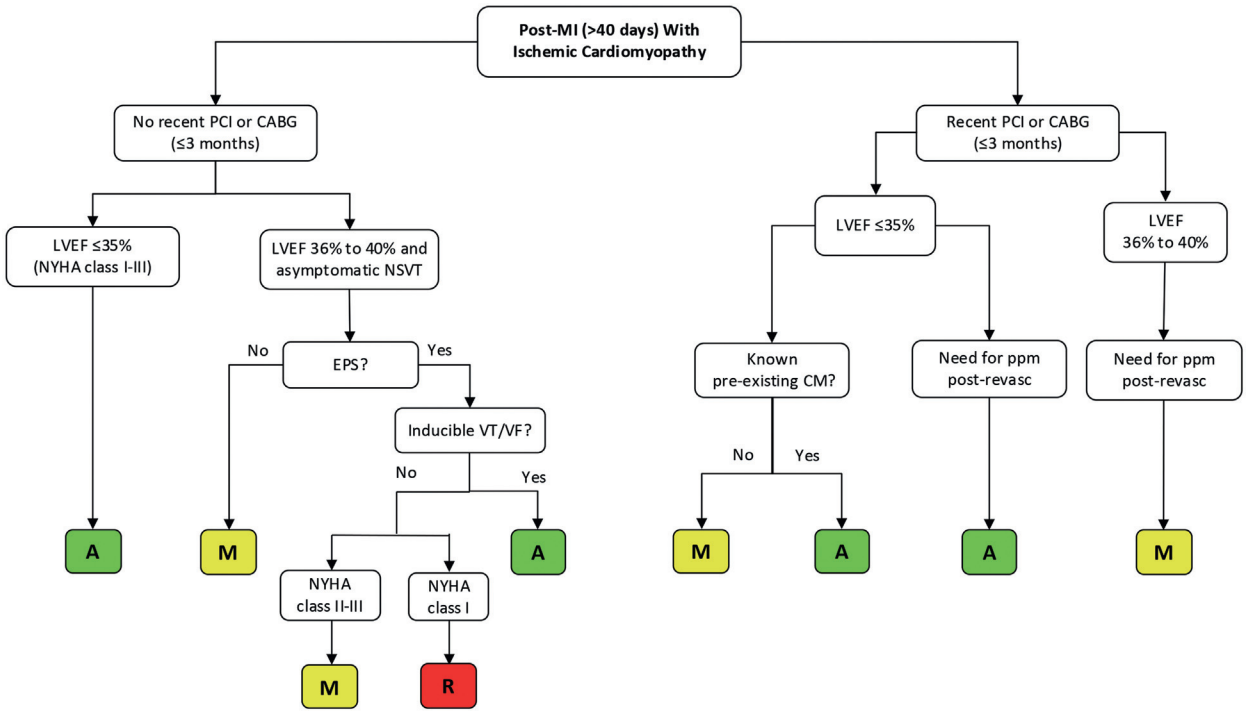
A = Appropriate; CAD = coronary artery disease; EPS = electrophysiological study; LVEF = left ventricular ejection fraction; M = May Be Appropriate; MI = myocardial infarction; NSVT = nonsustained ventricular tachycardia; R = Rarely Appropriate; VT = ventricular tachycardia.

early period may represent a less specific risk factor for future events, decisions related to timing of EP testing should be individualized. As in other areas of this AUC document, panel members were asked to evaluate scenarios where gaps in the guidelines exist, and further investigation may be warranted.

Pre-Existing CM or Permanent PM Needed

Despite a pre-existing CM with LVEF ≤35% present for ≥3 months prior to acute MI, results of IRIS and DINAMIT do not support routine ICD implantation within 40 days post-MI. Pre-existing CM with LVEF ≤35% present for ≥3 months prior to revascularization similarly does not indicate routine ICD implantation within 3 months of revascularization, regardless of the cause. Exclusion criteria for MADIT II required a waiting period of 3 months post-coronary revascularization,[55] and LVEF may improve after revascularization; however, when the LVEF is severely reduced (≤35%) and the patient requires permanent PM implantation early (≤40 days) following MI or (≤3 months) after revascularization, ICD therapy is preferable to PM implantation (Table 2.1.4). Although these scenarios are not specifically addressed in clinical trials, this is a logical decision from the standpoint of cost and patient safety. If little or no improvement in LV function is expected, the need for a second procedure in 3 months would expose the patient to unnecessary risk. When a patient requires pacing early (≤40 days) post-MI, implantation is also justified to avoid the expense and risk of implanting a PM followed by replacement with an ICD after the 40-day interval. In the REPLACE registry, a high complication rate of 15.3% was observed in patients undergoing planned transvenous lead addition for replacement or upgrade to a device capable of additional therapies.[57] These scenarios are addressed in a "2014 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."[58]

FIGURE 10 Summary of Tables 2.1.3 and 2.1.5, Primary Prevention, CAD



A = Appropriate; CABG = coronary artery bypass graft surgery; CM = cardiomyopathy; EPS = electrophysiological study; LVEF = left ventricular ejection fraction; M = May Be Appropriate; MI = myocardial infarction; NSVT = nonsustained ventricular tachycardia; PCI = percutaneous coronary intervention; PPM = permanent pacemaker; R = Rarely Appropriate; VF = ventricular fibrillation; VT = ventricular tachycardia.

Duration of GDMT

It is generally recommended that patients receive a period of GDMT following a new diagnosis of nonischemic or ischemic CM with the hope that LV function will improve. SCD-HeFT (Sudden Cardiac Death in Heart Failure Trial), which randomized ischemic and nonischemic CM patients with NYHA functional class II to III and LVEF ≤35% to amiodarone, placebo, or ICD implantation, required medical management of HF for ≥3 months prior to enrollment.[59,60] Exceptions for earlier ICD implantation in ischemic CM may include NSVT ≥4 days post-MI with EP study revealing inducible sustained VT (as in MUSTT) or need for permanent pacing early after revascularization and LVEF ≤35%. Since these earlier studies did not include SGLT2is and MRAs, GDMT in the current era may be even more effective to improve both the LVEF and survival.

2.2. Nonischemic CM

Assumptions and Considerations

- If magnetic resonance imaging (MRI) is performed as part of the scenario, it is assumed that it is performed at an expert MRI center with experienced imaging specialists.
- For those who underwent MRI and had late gadolinium enhancement (LGE), it is classified as either “present” or “absent” (and not quantified as above or below a specific threshold proportion).
- It is assumed that this is not a newly diagnosed CM (ie, within 3 months) unless otherwise specified.
- If NYHA functional class ≥II and LBBB, it is assumed that the patient will also be a candidate for CRT if appropriate for the scenario.
- Scenarios assume that an idiopathic nonischemic CM is present.
- For GDMT, it is assumed this includes a beta-blocker, aldosterone antagonist (when possible), angiotensin-converting enzyme inhibitor or angiotensin receptor blocker, or sacubitril-valsartan when indicated, unless otherwise specified.

According to the 2017 AHA/ACC/HRS Guideline for Management of Patients with Ventricular Arrhythmias and the Prevention of Sudden Cardiac Death, recommendations for ICD implantation for patients with nonischemic CM are independent of age.[4] On the other hand,

age affects outcomes because of competing mortalities and affects choices in shared decision making.[61,62] In DANISH (Danish Study to Assess the Efficacy of ICDs in Patients with Non-Ischemic Systolic Heart Failure on Mortality), which did not show benefit of ICD therapy above optimized medical therapy, a substudy that must be interpreted in the context that the primary endpoint was negative suggested benefit for younger (age ≤70 years) compared with older patients.[63,64] Furthermore, optimized therapy in the DANISH trial did not include sacubitril/valsartan, which decreases mortality an additional 20% compared with that of treatment with an angiotensin-converting enzyme inhibitor.[65] Similarly, because earlier studies did not include SGLT2is and MRAs, GDMT in the current era using these drugs may further improve the LVEF and survival. In view of the challenges of identifying patients most likely to benefit from ICD therapy, cardiac MRI has been used for risk stratification. Patients with LGE have higher mortality risk compared with those without, but randomized clinical trial data showing ICD benefit for them is lacking. Whereas individual studies[66,67] and meta-analyses[68] suggest that LGE identifies patients who benefit from ICD therapy, a substudy of the DANISH trial indicates that patients with LGE on cardiac MRI have decreased survival compared with those without LGE, whereas ICD therapy did not improve survival in patients with LGE.[69]

Newly Diagnosed Nonischemic CM

The management of newly diagnosed CM depends on the severity of decompensation. For those who are hemodynamically stable, there are no data to support benefit of early ICD implantation.[59,69-71] For example, in the SCD-HeFT trial, which required 3 months of optimized medical therapy before randomization to receive an ICD, there was no difference in survival during the first year in those treated with an ICD vs optimized medical therapy alone. When myocarditis is 1 cause of newly diagnosed CM, there are guidelines for its management[72] but no randomized, controlled trial data regarding ICD implantation. Especially for giant-cell myocarditis, ventricular arrhythmias are common and ICD implantation might be considered,[4] but for etiologies other than sarcoidosis and Chagas disease, the guidelines are silent especially when ventricular arrhythmias are absent. When optimized medical therapy has been provided for 3 months, ICD implantation is recommended if LVEF remains ≤35%. There are no randomized trials addressing the role of ICD therapy in patients with cardiac transplantation.

Nonischemic CM and Need for Pacing

In regard to pacing in nonischemic CM, standard indications are operative.[7] This is especially important as related to the DANISH trial, in which 58% of patients in both the ICD and control groups underwent CRT for appropriate indications. Indeed, 1 part of the explanation for the low mortality in both groups is that CRT is just 1 component of optimized therapy and that when it is provided with optimized drug therapy, outcomes are greatly improved making the addition of an ICD less able to provide further benefit.

Nonischemic CM, Specific Etiologies and Genetic Conditions

As noted in the secondary prevention section, nonischemic CM is not a single disease and may have multiple etiologies. Chronicity and potential reversibility as well as long-term prognosis may vary based on specific etiology. For example, medical therapy may result in a near-complete reversal with ventricular reverse remodeling in a patient with a peripartum CM or with a tachycardia-induced CM, whereas prognosis may be poor for patients who have some forms of infiltrative CM. Genetic conditions associated with CM may vary with respect to prognosis. Arrhythmogenic CM is defined as an arrhythmogenic disorder of the myocardium that is not secondary to ischemic, hypertensive, or valvular heart disease, and incorporates a broad spectrum of disorders that includes—but is not limited to—arrhythmogenic RV CM, cardiac amyloidosis, sarcoidosis, Chagas disease, and LV noncompaction.[73] The 2019 HRS expert consensus document describes the evaluation, risk stratification, and management of arrhythmogenic CM.[73]

Tables 2.2.1 to 2.4 and **Figures 11 to 14** describe primary prevention ICD indications in patients with nonischemic CM modified by LVEF, NYHA functional class, age, treatment duration, and need for pacing, as well as specific genetic conditions with and without associated structural heart disease.

Section 2 Results and Discussion

Primary prevention ICD implantation may be considered in a variety of scenarios to reduce mortality related to potentially life-threatening sustained ventricular arrhythmias in patients without any prior history of sustained VT/VF or syncope. Specific time periods for implantation of primary prevention ICDs (ie, 40 days after an acute MI, 3 months after revascularization, and 3 months after initial diagnosis of a CM) are described in various scenarios (**Tables 2.1.1 to 2.1.6**, **Figures 9 and 10**). These time periods were selected for this appropriate use document based on prior clinical trials, guideline documents, or contemporary practice. A "waiting period" following MI is supported by the IRIS trial and DINAMIT, which demonstrated no overall survival benefit of ICD therapy when devices were implanted very early (within 30 or 40 days) following MI.[51,52] Scenarios in this section are also modified by type of heart disease, LVEF, NYHA functional class, and/or duration of GDMT (Tables 2.1 to 2.2, **Figures 9 to 13**).

TABLE 2.2.1 Nonischemic Cardiomyopathy and Treatment Duration

Indication	Appropriate Use Score (1-9)	
Treatment Since Diagnosis <3 Months **Newly Diagnosed Idiopathic Nonischemic Cardiomyopathy**		
NYHA Functional Class	**I**	**II-III**
107. ■ <35 years of age ■ LVEF ≤35% ■ Normal QRS duration	R (2)	R (3)
108. ■ 35-64 years of age ■ LVEF ≤35% ■ Normal QRS duration	R (2)	R (3)
109. ■ 65-84 years of age ■ LVEF ≤35% ■ Normal QRS duration	R (2)	R (3)
110. ■ ≥85 years of age ■ LVEF ≤35% ■ Normal QRS duration	R (2)	R (2)
111. ■ LVEF >35%-49% ■ LGE present on MRI	R (3)	R (3)
On Guideline-Directed Medical Therapy for ≥3 Months **Idiopathic Nonischemic Cardiomyopathy**		
NYHA Functional Class	**I**	**II-III**
112. ■ <35 years of age ■ LVEF ≤35% ■ Normal QRS duration	A (7)	A (8)
113. ■ 35-64 years of age ■ LVEF ≤35% ■ Normal QRS duration	A (7)	A (9)
114. ■ 65-84 years of age ■ LVEF ≤35% ■ Normal QRS duration	A (7)	A (8)
115. ■ ≥85 years of age ■ LVEF ≤35% ■ Normal QRS duration	M (5)	M (6)
116. ■ LVEF >35%-49% ■ LGE present on MRI	M (5)	M (6)
117. ■ LVEF ≤35% ■ On medical therapy including beta-blocker, ACE inhibitor, or ARB, but not sacubitril-valsartan	A (7)	A (8)

A = Appropriate; ACE = angiotensin-converting enzyme; ARB = angiotensin receptor blocker; LGE = late gadolinium enhancement; LVEF = left ventricular ejection fraction; M = May Be Appropriate; MRI = magnetic resonance imaging; NYHA = New York Heart Association; R = Rarely Appropriate.

TABLE 2.2.2 Nonischemic Cardiomyopathy and Need for Pacing After Valve Intervention

Indication	Appropriate Use Score (1-9)
Recent Valve Surgery (ie, Same Hospitalization or <3 Months), Which Included Incidental Bypass Graft	
118. ■ LVEF ≤35% ■ Need for pacemaker and LV function felt not likely to improve	A (7)
Recent TAVR, Same Hospitalization	
119. ■ LVEF ≤35% ■ Need for pacemaker and LV function felt not likely to improve	A (7)

A = Appropriate; LVEF = left ventricular ejection fraction; LV = left ventricular; TAVR = transcatheter aortic valve replacement.

Timing Post-MI or Revascularization and EP Testing

Initial primary prevention ICD trials utilized EP testing in risk stratification. Many of the scenarios in Tables 2.1.1 to 2.1.2 describe some of the shorter time periods post-MI (≤40 days) where limited trial data are available. MUSTT enrolled patients with CAD, LVEF ≤40%, and asymptomatic, nonsustained VT.[54] The qualifying arrhythmia had to have occurred within 6 months before enrollment and ≥4 days after the most recent MI or revascularization procedure. The study showed that EP-guided therapy with ICDs, but not with antiarrhythmic drugs, reduced the risk of sudden death; however, most (>80%) of randomized patients had their most recent MI >1 month before enrollment. Thus, because few patients were enrolled in the first month post-MI, the utility of EP testing in that time period is uncertain. Nonetheless, ICD implantation is considered Appropriate if in patients early post-MI (≤40 days) in the setting of asymptomatic NSVT occurring ≥4 days post-MI if sustained VT is inducible by EP study in patients with LVEF ≤40% (Tables 2.1.1 to 2.1.2, Figure 9). This is consistent with results from the MUSTT trial.

Several scenarios are also modified by the presence or absence of revascularization. To qualify for enrollment, the MADIT II trial required a waiting period of ≥3 months following coronary revascularization.[55] In contrast, patients were eligible for enrollment in the MUSTT trial ≥4 days following revascularization, and 56% of patients enrolled in this trial underwent prior CABG at some point in time.[54] However, post-hoc analysis of the MUSTT trial revealed that the occurrence of postoperative NSVT, especially within 10 days after CABG, portends a far better outcome than when it occurs in non-postoperative settings.[56] Nonetheless, ICD implantation is considered

TABLE 2.2.3 Nonischemic Cardiomyopathy, Specific Etiologies

Indication	Appropriate Use Score (1-9)	
Specific Etiologies, on Guideline-Directed Medical Therapy for <3 Months		
LVEF	**≤35%**	**>35%**
120. ■ Sarcoid heart disease, no MRI performed	A (7)	M (6)
121. ■ Myotonic dystrophy	A (8)	M (5)
122. ■ Chagas disease	A (8)	M (6)
123. ■ Amyloidosis with heart failure	M (6)	M (5)
124. ■ Acute lymphocytic myocarditis	M (4)	R (3)
125. ■ Giant-cell myocarditis	A (8)	A (7)
Peripartum Cardiomyopathy, on Guideline-Directed Medical Therapy for ≥3 Months		
126. ■ Peripartum cardiomyopathy ■ Persists >3 months postpartum	A (7)	R (3)

A = Appropriate; LVEF = left ventricular ejection fraction; M = May Be Appropriate; MI = myocardial infarction; MRI = magnetic resonance imaging; R = Rarely Appropriate.

TABLE 2.3 Genetic Conditions With Structural Heart DiseaseAssumptions and Considerations

Indication	Appropriate Use Score (1-9)
Genetic Arrhythmogenic Cardiomyopathies Associated With Sudden Cardiac Death	
127. ■ Hypertrophic cardiomyopathy with ≥1 risk factor*	A (8)
128. ■ Arrhythmogenic right ventricular dysplasia/CM with no symptoms due to arrhythmia	A (7)
129. ■ Evidence of structural cardiac disease with Lamin A/C mutation or other genetic ACM but LVEF >35% and <45%	A (7)
130. ■ Normal ECG and echo but carrying the implicated gene	M (4)
131. ■ LV noncompaction with LVEF >35%	M (5)

*Risk factors include maximum LV wall thickness ≥30 mm, SCD in ≥1 first-degree relatives presumably caused by HCM, ≥1 episodes of unexplained syncope within the preceding 6 months, spontaneous NSVT, and an abnormal blood pressure response with exercise.

A = Appropriate; ACM = arrhythmogenic cardiomyopathy; CM = cardiomyopathy; ECG = electrocardiogram; echo = echocardiogram; LV = left ventricular; LVEF = left ventricular ejection fraction; M = May Be Appropriate; NSVT = nonsustained ventricular tachycardia.

Appropriate after revascularization following acute MI (≤40 days) in the setting of asymptomatic NSVT (>4 days post-MI) if sustained VT is inducible by EP study in patients with LVEF ≤40% (Tables 2.1.1 to 2.1.2, Figure 9). As there are limited data related to EP testing very early following revascularization, and available data suggest that NSVT in this early period may represent a less specific risk factor for future events, decisions related to timing of EP testing should be individualized.

TABLE 2.4 Genetic Conditions Without Structural Heart Disease

Indication	Appropriate Use Score (1-9)
Congenital Long QT Syndrome, With 1 or More Risk Factors,* Asymptomatic	
132. ■ Not receiving evidence-based beta-blocker ■ Resting QTc <470 ms	M (4)
133. ■ Receiving evidence-based beta-blocker ■ Resting QTc >500 ms	M (6)
Catecholaminergic Polymorphic VT With Nonsustained VT (Without Syncope)	
134. ■ Not receiving beta-blockers, flecainide, or propafenone	R (3)
135. ■ Receiving medical therapy (beta-blockers, flecainide, or propafenone)	M (5)
136. ■ Not tolerating medical therapy or breakthrough nonsustained ventricular arrhythmias on medical therapy (beta-blockers, flecainide, or propafenone)	A (8)
Spontaneous, Incidentally Discovered Brugada by ECG (Type I ECG Pattern) In the Absence of Symptoms or Family History of Sudden Cardiac Death	
137. ■ No EPS	R (3)
138. ■ Inducible VT or VF at EPS	A (7)
139. ■ No inducible VT or VF at EPS	R (3)

*Risk factors include QTc >500 ms, genotypes Long QT2 or Long QT3, <40 years of age, onset of symptoms <10 years of age, prior cardiac arrest, or recurrent syncope.

A = Appropriate; ECG = electrocardiogram; EPS = electrophysiology study; M = May Be Appropriate; R = Rarely Appropriate; VF = ventricular fibrillation; VT = ventricular tachycardia.

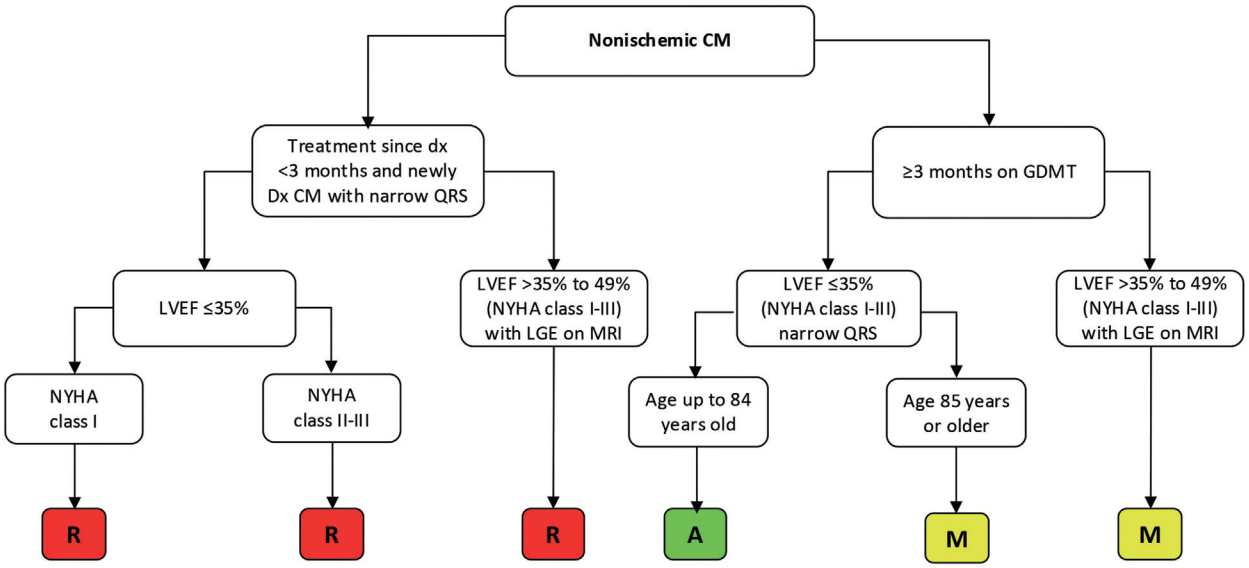
Pre-Existing CM or Permanent PM Needed

When a pre-existing chronic (≥3 months) CM with LVEF ≤35% has been present for ≥3 months, regardless of the cause, ICD implantation was rated Appropriate even within 40 days after acute MI (Table 2.1.3, Figure 10). The rationale for this scenario is that the CM was a pre-existing condition not attributable to acute MI and, therefore, LVEF would not be likely to recover. When recent (≤3 months) revascularization has been performed, the rating panel determined that an ICD implantation was Appropriate when there was a known pre-existing CM with LVEF ≤35% on GDMT for ≥3 months prior to percutaneous coronary intervention/CABG (Table 2.1.5, Figure 10). In addition, when the LVEF is severely reduced (≤35%) and the patient requires permanent PM implantation early (≤40 days) following MI or <3 months following revascularization, ICD therapy was rated Appropriate (Tables 2.1.4 to 2.1.5, Figure 10). Although these scenarios are not specifically addressed in clinical trials, this is a logical decision from the standpoint of cost and patient safety. If little or no improvement in LV function is expected following revascularization, the need for a second procedure in 3 months would expose the patient to unnecessary risk. When a patient requires pacing early (≤40 days) post-MI, implantation is also justified to avoid the expense and risk of implanting a PM followed by replacement with an ICD after the 40-day interval. In the REPLACE Registry, a high complication rate of 15.3% was observed in patients undergoing planned transvenous lead addition for replacement or device upgrade.[57] Implanting the ICD earlier would avoid the additional risks associated with early reoperation.

Duration of GDMT

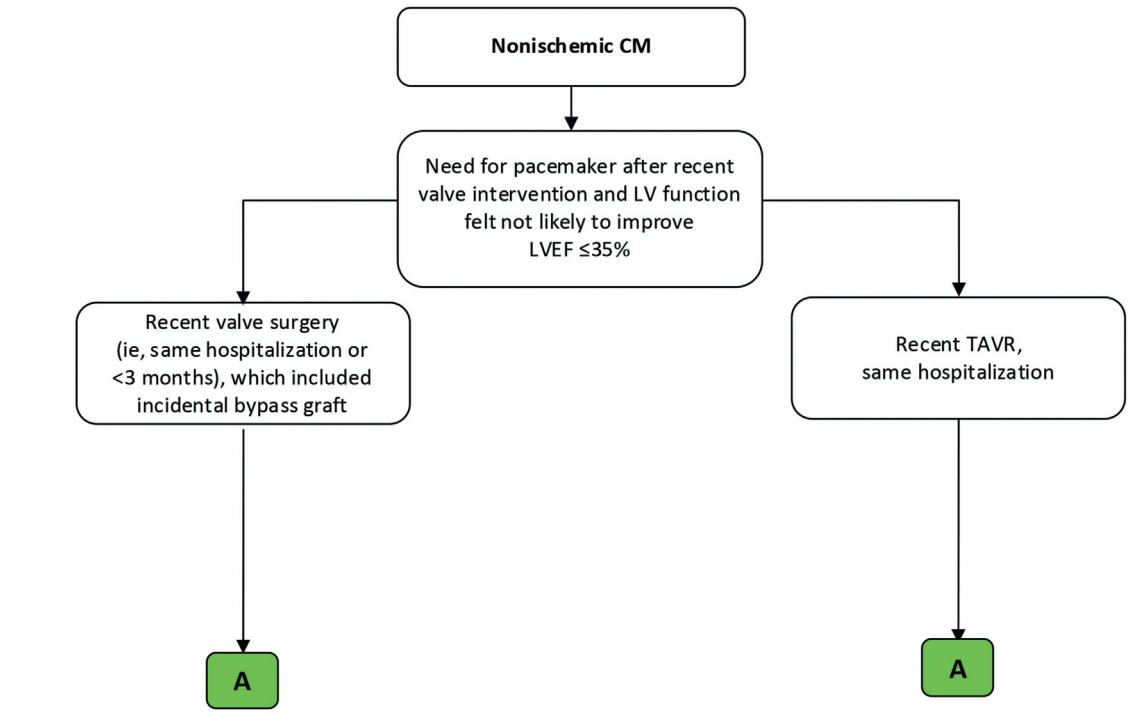
Once a patient with a nonischemic CM is on GDMT for ≥3 months, ICD implantation was rated Appropriate for LVEF ≤35%, narrow QRS, and NYHA functional class I-III symptoms if <85 years of age and was rated May Be Appropriate if ≥85 years of age (Table 2.2.1, Figure 11). It is generally recommended that patients receive a period of GDMT following a new diagnosis of nonischemic CM with the hope that LV function will improve. ICD implantation within 3 months of a newly diagnosed CM (LVEF ≤35%) was considered Rarely Appropriate in most instances (Table 2.2.1, Figure 11). Similarly, in the setting of an ischemic CM without recent MI, ICD implantation was deemed Appropriate only after the patient had received GDMT for ≥3 months, unless NSVT had been present and EP study revealed inducible sustained VT/VF (Table 2.1.6).

FIGURE 11 Summary of Table 2.2.1, Primary Prevention: Nonischemic Cardiomyopathy and Treatment Duration



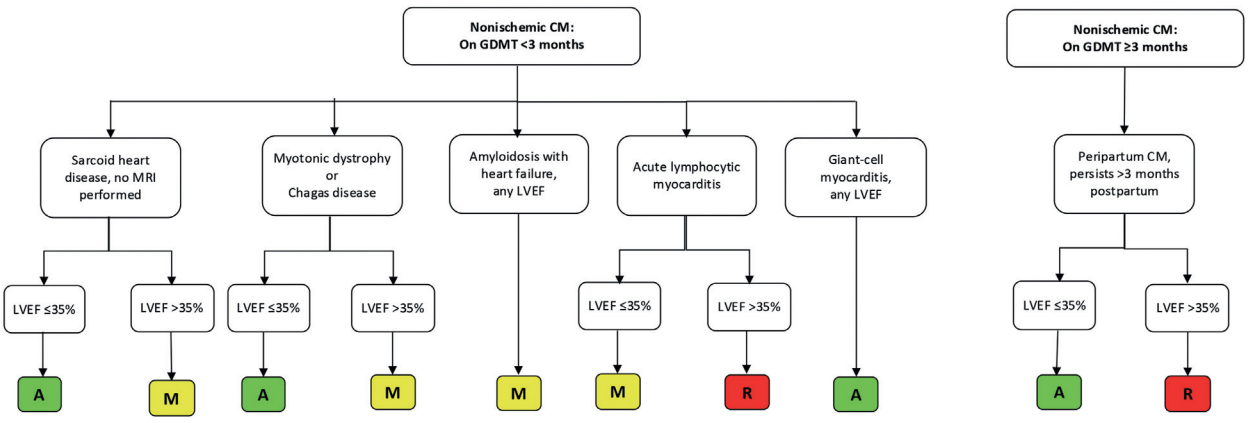
A = Appropriate; CM = cardiomyopathy; Dx = diagnosed; GDMT = guideline-directed medical therapy; LGE = late gadolinium enhancement; LVEF = left ventricular ejection fraction; M = May Be Appropriate; MRI = magnetic resonance imaging; NYHA = New York Heart Association; R = Rarely Appropriate.

FIGURE 12 Summary of Table 2.2.2, Primary Prevention: Nonischemic Cardiomyopathy and Need for Pacing After Valve Intervention



A = Appropriate; CM = cardiomyopathy; LV = left ventricle; LVEF = left ventricular ejection fraction; TAVR = transcatheter aortic valve repair.

FIGURE 13 Summary of Table 2.2.3, Nonischemic CM, Specific Etiologies

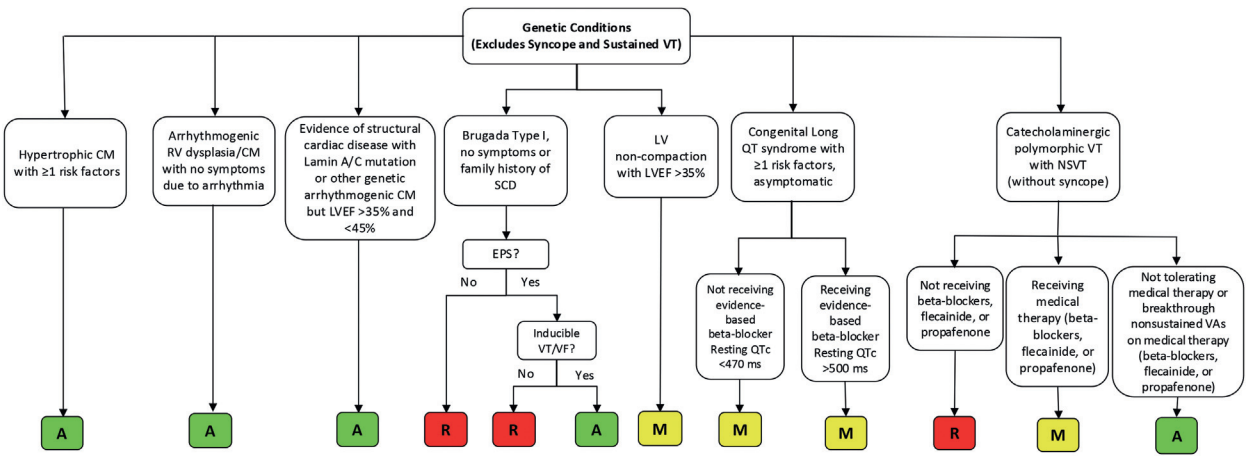


A = Appropriate; CM = cardiomyopathy; GDMT = guideline-directed medical therapy; LVEF = left ventricular ejection fraction; M = May Be Appropriate; MRI = magnetic resonance imaging; R = Rarely Appropriate.

Another potential exception to the 3-month waiting period is when pacing is needed after recent valve surgery with an incidental bypass graft, and severe LV function (LVEF ≤35%) is not likely to improve (Table 2.2.2, Figure 12). Additional potential exceptions to the 3-month rule may also apply to specific etiologies for nonischemic CM as noted in Table 2.2.3 as significant improvement in LV function or arrhythmic substrate are not anticipated despite GDMT. For example, ICD implantation was considered Appropriate by the rating panel for patients with sarcoid heart disease, myotonic dystrophy, Chagas disease, and giant-cell myocarditis if LVEF ≤35% on GDMT for <3 months as these syndromes are associated with high risk for arrhythmias (Table 2.2.3, Figure 13).

In addition, medical therapy may not have a significant role in improving ventricular dysfunction or reducing arrhythmic in genetic arrhythmogenic

FIGURE 14 Summary of Table 2.3, Primary Prevention: Genetic Conditions With Structural Heart Disease



*Risk factors include maximum LV wall thickness ≥30 mm, SCD in ≥1 first-degree relative presumably caused by HCM, ≥1 episode of unexplained syncope within the preceding 6 months, spontaneous NSVT, and an abnormal blood pressure response with exercise. A = Appropriate; ACM = arrhythmogenic cardiomyopathy; CM = cardiomyopathy; EPS = electrophysiology study; HCM = hypertrophic cardiomyopathy; LV = left ventricle; LVEF = left ventricular ejection fraction; M = May Be Appropriate; NSVT = nonsustained ventricular tachycardia; R = Rarely Appropriate; RV = right ventricular; SCD = sudden cardiac death; VA = ventricular arrhythmia; VF = ventricular fibrillation; VT = ventricular tachycardia.

cardiomyopathies. For example, ICD implantation for primary prevention is considered Appropriate in hypertrophic CM with ≥1 risk factor, arrhythmogenic RV CM without symptoms, and structural heart disease with Lamin A/C mutation or other genetic arrhythmogenic CM even if LVEF >35% and <45%, and May Be Appropriate for LV noncompaction with LVEF >35% (**Table 2.3**, **Figure 14**). Other genetic conditions without structural heart disease, such as asymptomatic congenital long QT syndrome, catecholaminergic PMVT with NSVT, or incidentally discovered Brugada (type 1 ECG pattern), were rated at various levels of appropriateness that may be modified by medical therapy or results other testing (**Table 2.4**, **Figure 14**).

Section 3: Comorbidities

It should be noted that the scenarios in this section refer to ICDs implanted for *primary prevention*.

Assumptions and Considerations

- Assume the "best" device choice for the particular patient will be selected, unless otherwise specified, ie, single, dual, CRT, or transvenous vs totally subcutaneous.

A primary prevention ICD in patients who have HF with reduced EF with comorbidities overall suggests a decreased ICD mortality benefit with advancing age,[63,74] diabetes,[75,76] chronic kidney disease (CKD) (including dialysis),[77,78] comorbidities,[62,79] advanced NYHA functional class,[80] lower 6-minute walk test (6MWT) distance,[81] frailty,[82] and increased all-cause annual mortality.[83-86] A unifying concept suggests there is less ICD benefit as the competing risk of nonsudden death increases.[28,29,85,87-89]

In the SCD-HeFT trial, patients with a Seattle Heart Failure Model estimated mortality of >20%/y had no benefit from an ICD.[90] Similar findings were demonstrated in the MADIT II trial, with decreased benefit as the all-cause mortality increased as estimated by the MADIT II Risk Model.[84,91]

A meta-analysis of 5 primary prevention ICD trials demonstrated a decreased ICD benefit in patients with Charlson Comorbidity Index ≥2 (HR: 0.59 vs 0.71).[62] Significant CKD and diabetes mellitus appear to diminish ICD benefit. In the MADIT II trial, patients with a blood urea nitrogen >50 mg/dL or creatinine ≥2.5 mg/dL were very high risk and had no ICD benefit.[84] An estimated glomerular filtration rate of <60 mL/min/1.73 m^2 was associated with a marked reduction in ICD benefit in prevention of sudden death (HR: 0.68 vs 0.22) and all-cause mortality (HR: 0.80 vs 0.49).[78] Patients receiving dialysis have an increased risk of sudden death. The ICD2 (Implantable Cardioverter-Defibrillator in Dialysis Patients) trial evaluated ICDs in patients (EF >35%) receiving dialysis.[92] The trial did not show a reduction in either sudden death or all-cause mortality with ICDs.

Patients with diabetes have been reported to have an increased risk of sudden death. Although patients with diabetes had increased mortality, the rate of appropriate ICD therapy was lower, suggesting that sudden death associated with diabetes may not be due to tachyarrhythmias.[75] In a meta-analysis, there was no benefit of ICDs in patients with vs without diabetes mellitus (HR: 0.88 vs 0.56).[93] It is quite likely that other comorbidities that increase the competing risk of nonsudden death, such as cirrhosis, dementia, cancer, and lung disease, may also be associated with decreased benefit from a primary prevention ICD.[94,95]

Advancing age is associated with a greater increase in nonsudden death than sudden death, resulting in a decrease in the proportion of death due to sudden death.[96] Primary prevention ICDs have been associated with attenuated ICD benefit in a meta-analysis, although patients aged >75 years still had benefit.[74] In the DANISH trial, patients with age >70 years with nonischemic CM had no benefit from an ICD.[63]

Several risk models have been used to try to identify patients who will derive greater benefit from an ICD. The MADIT II model identified 5 variables, age >70 years, NYHA functional class >II, blood urea nitrogen >26 mg/dL, atrial fibrillation, and QRS >120 ms.[84] The investigators found a U-shaped relationship with no benefit with 0 variables or very high-risk patients with blood urea nitrogen >50 mg/dL or creatinine >2.5 mg/dL; however, in the 8-year follow up of the MADIT II trial, the maximum benefit was in those with 0 risk variables and the interaction of risk variables with ICD benefit was not significant.[91]

The Seattle Heart Failure Model was derived to predict all-cause mortality in mainly patients with HF with reduced EF. Lower-risk patients had a higher proportion of sudden death, whereas higher-risk patients had a higher proportion of HF death.[97] This model was tested in the SCD-HeFT trial.[90] The benefit of the ICD in prevention of sudden death and all-cause mortality was attenuated, as the mortality estimate increased with no benefit with an annual mortality of greater than approximately 20%.

An alternative approach of competing risk was used with the Seattle Proportional Risk Model, which predicts the proportion of sudden vs nonsudden death.[88] Ten variables were found to be independently associated with an increased proportion of sudden death: younger age, lower NYHA functional class, lower ejection fraction, higher body mass index, male sex, systolic blood pressure near 140 mm Hg, lack of diabetes mellitus, digoxin use, and serum sodium and creatinine in the normal range. The most powerful variables in the model were age,

creatinine level, body mass index, diabetes mellitus, and sex. Application of this model in observational and randomized ICD trials demonstrated that patients with a higher proportion of predicted sudden death derive a greater ICD benefit in prevention of sudden death and all-cause mortality.[28,29,85,87]

Other approaches have attempted to predict ICD shock/therapy and/or all-cause mortality. These models do not purport to estimate the ICD benefit but rather compare ICD shock rates and all-cause mortality.[94,95,98]

Table 3.1 and **Figure 15** describe scenarios including specific conditions or comorbidities that may impact on the decision to implant an ICD for primary prevention indications.

Section 3 Results and Discussion

The benefits and risks of ICD therapy may be modified by specific coexisting comorbidities, even when other primary prevention indications exist for ICD implantation. Comorbidities may limit life expectancy or increase procedural risk. The potential risks and benefits should be assessed on an individual basis, and options should be discussed between the healthcare provider and the individual patient using shared decision making. The writing group created scenarios with specific comorbidities that may modify decision making regarding primary prevention ICD implantation when the ICD would otherwise meet criteria for implantation.

Comorbidities that were felt to make ICD implantation Rarely Appropriate include a life expectancy <1 year, age >90 years with NYHA functional class I to III symptoms, inability to understand or provide informed consent in the absence of a healthcare proxy, significant psychiatric illness that may be aggravated by device implantation or that may preclude regular follow-up, ongoing intravenous drug abuse, unresolved infection associated with risk for hematogenous seeding with a planned transvenous implantable cardioverter-defibrillator (TV-ICD), nonadherence with medical therapy and follow-up, or certain NYHA functional class IV patients, such as those who are not candidates for advanced therapies (ie, cardiac transplantation, CRT, or ventricular assist device) (**Table 3.1**, **Figure 15**). There are many degrees and reasons for nonadherence with medical therapy and follow-up, some of which can be improved through better education and enhanced access to care. Therefore, the individual patient situation should clearly be considered prior to determining eligibility for ICD therapy.

Among the considered comorbidities, ICD implantation was considered May Be Appropriate for patients with noncardiac disease who have a life expectancy of 1 to 2 years or those who are 80 to 90 years of age. Although SCD increases with age, elderly patients have been underrepresented in clinical trials, and comorbidities in the elderly might attenuate the benefit of ICD therapy. There is evidence that older patients with ICDs have lower survival rates than those of younger patients because death related to comorbidities in elderly patients outweighs the proportion of deaths related to ventricular arrhythmias.[74] In addition, characteristics of patients receiving ICDs in clinical practice may differ from those enrolled in randomized clinical trials. For example, in primary prevention ICD trials, the median or mean age was only 60 to 67 years.[50,54,55,99] In contrast, real-world data show a significant percentage of more elderly patients receiving ICD therapy. In the Advancements in ICD Therapy Registry, which included 4,566 patients who underwent their first ICD implantation procedure, 12% were ≥80 years of age (75% of whom received devices for primary prevention), which was similar to the NCDR (N = 74,476 patients) at that time where 12.4% of patients receiving ICDs were ≥80 years of age.[100] As expected, the cause of death was more likely noncardiac in older than in younger patients. In a subsequent report of NCDR data, 16.8% of patients receiving ICDs were ≥80 years of age and 75% of ICDs implanted in all patients were for primary prevention.[101]

Prior studies have questioned the benefit of ICD implantation in patients with CKD, especially in patients on dialysis.[92,102,103] ICD implantation for primary prevention was considered May Be Appropriate for patients with CKD on dialysis or CKD with creatinine clearance <30 mL/min and not yet on dialysis (but candidates for dialysis). CKD and associated comorbidities reduce long-term survival of patients and limit the beneficial impact of ICD therapy. Patients with CKD who are on dialysis are also at higher risk of complications related to ICD implantation, including increased risks related to bleeding and infection.[104,105] Due to the increased risk for endovascular infection in patients on chronic dialysis, the subcutaneous ICD is now often considered as an alternative to TV-ICD systems.[106]

ICD implantation can serve as a bridge to transplantation by preventing SCD in the outpatient setting. For NYHA functional class IV patients who are on a waiting list for heart transplant (outpatient status), ICD implantation was considered Appropriate, whereas ICD implantation for ambulatory NYHA functional class IV outpatients with an LVAD was considered May Be Appropriate (**Table 3.1**, **Figure 15**). In the setting of NYHA functional class IV HF, if the patient is not deemed to be a candidate for cardiac transplantation, CRT, or ventricular assist device, ICD therapy was rated Rarely Appropriate when refractory symptoms on oral medical therapy are

TABLE 3.1 Special Conditions/Comorbidities in Patients for Primary Prevention (Meeting Indications of ICD Implant Related to HF Diagnosis With LVEF ≤30% on Guideline-Directed Medical Therapy >3 Months)

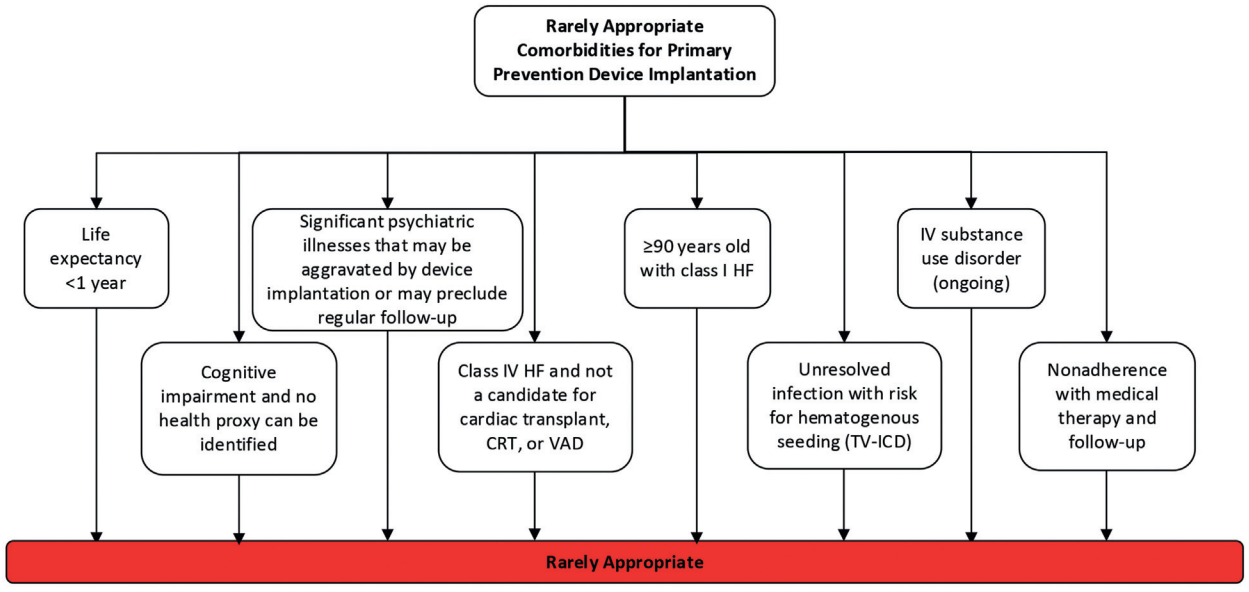
Indication				Appropriate Use Score (1-9)
Life Expectancy				
140.	■ Life expectancy <1 year from cardiac or noncardiac conditions			R (1)
141.	■ Noncardiac disease with life expectancy 1-2 years			M (4)
Elderly				
NYHA Functional Class		I	II	III
142.	■ 80-84 years of age	M (5)	M (6)	M (6)
143.	■ 85-89 years of age	M (4)	M (5)	M (5)
144.	■ ≥90 years of age	R (3)	M (4)	R (3)
Cognitive Impairment				Appropriate Use Score (1-9)
145.	■ Not able to understand or provide informed consent ■ Healthcare proxy consents to ICD			M (4)
146.	■ Not able to understand or provide informed consent ■ No healthcare proxy can be identified			R (2)
Advanced Psychiatric Impairment				
147.	■ Significant psychiatric illnesses that may be aggravated by device implantation or that may preclude regular follow-up			R (1)
Chronic Kidney Disease				
NYHA Functional Class		I	II	III
148.	■ Chronic kidney disease on dialysis ■ No pacing or CRT indication ■ Implant transvenous ICD	M (5)	M (5)	M (4)
149.	■ Chronic kidney disease with CrCl <30 mL/min not yet on dialysis but candidate for dialysis ■ No pacing or CRT indication ■ Implant transvenous ICD	M (5)	M (5)	M (5)
Other Comorbidities or Special Patient Situations				
Special Risks for Infection				Appropriate Use Score
150.	■ IV substance use disorder (ongoing) ■ Implant transvenous ICD			R (2)
151.	■ Unresolved infection associated with risk for hematogenous seeding ■ Implant transvenous ICD			R (2)
Medical Adherence				Appropriate Use Score
152.	■ Nonadherence with medical therapy and follow-up			R (3)
Class IV HF				Appropriate Use Score
153.	■ On waiting list for heart transplant (outpatient status)			A (7)
154.	■ Not candidate for cardiac transplantation, CRT, or VAD ■ Refractory symptoms on oral therapy			R (2)
155.	■ Ambulatory outpatient with an LVAD			M (4)
156.	■ Not a candidate for transplant or VAD ■ Does not meet CRT criteria ■ Planned outpatient continuous intravenous inotropic therapy for palliation			R (2)

A = Appropriate; CrCl = creatinine clearance; CRT = cardiac resynchronization therapy; HF = heart failure; ICD = implantable cardioverter-defibrillator; IV = intravenous; LVAD = left ventricular assist device; LVEF = left ventricular ejection fraction; M = May Be Appropriate; NYHA = New York Heart Association; R = Rarely Appropriate; RV = right ventricular; VAD = ventricular assist device.

present or outpatient continuous inotropic therapy for palliation is planned (Table 3.1, Figure 15). This is consistent with an anticipated low survival rate for ≥1 year for NYHA functional class IV patients with drug-refractory HF who are not candidates for cardiac transplantation or CRT.

The survival benefit and complications related to primary prevention ICD implantation are impacted by age, HF class, candidacy for other interventions, and preexisting comorbidities such as chronic renal disease. Therefore, potential adverse influence of comorbidities should be openly discussed with potential ICD recipients

FIGURE 15 Summary of Table 3.1, Primary Prevention Comorbidities: Rarely Appropriate Indications



CRT = cardiac resynchronization therapy; HF = heart failure; ICD = implantable cardioverter-defibrillator; IV = intravenous; TV = transvenous; VAD = ventricular assist device.

prior to device implantation to enhance the informed decision-making process.

Section 4: ICD Generator Replacement at Elective Replacement Indicator

Assumptions and Considerations

- Assume shared decision making has taken place, particularly if there have been no clinically relevant ventricular arrhythmias since implant, now with a prognosis for survival <1 year.

There are limited data about the management of patients presenting for elective generator replacement in the setting of previously implanted ICD or CRT devices that are nearing end of life. During a patient's life span, clinical situations evolve and previously present conditions that merited ICD or CRT implantation may change. The individual patient's clinical status and concomitant illnesses may evolve so that considerations may include not only replacement of the pulse generator, but also potentially changing the type of device (eg, from an ICD to a PM). Furthermore, the clinical evidence for CIED placement may evolve across time, with ongoing research and availability of new trial data. Once patients have received appropriate ICD therapy for ventricular arrhythmias, they are subsequently considered "secondary prevention" at the time of generator replacement in the NCDR. There is currently a paucity of data related to generator replacement in patients who received primary prevention ICDs but have not experienced clinically relevant arrhythmias since initial implantation, and generator replacement is often still performed regardless of LVEF at follow-up; however, the decision to perform a generator replacement or consider "upgrade" of a device is not without risk. As previously noted, there was a high complication rate of 15.3% observed in the REPLACE Registry in patients undergoing planned transvenous lead addition for replacement or upgrade to a device capable of additional therapies.[57] Therefore, the indications seek to assess appropriateness for a variety of clinical scenarios related to either "replace the pre-existing CIED" or "downgrade" ICDs or CRT-ICDs to PMs.

Scenarios that consider the original indication for the device, life expectancy, interim ventricular arrhythmias, or LVEF recovery are described in Tables 4.1 to 4.4. Replacement of a CRT-ICD with a CRT PM when the LVEF has improved since initial device implantation for primary prevention indications is a scenario commonly encountered. Limited data suggest that arrhythmic risk is reduced in patients with improved LVEF, although in the MADIT-CRT (Multicenter Automatic Defibrillator Implantation Trial-Cardiac Resynchronization Therapy) trial substantial ventricular tachyarrhythmia risk remained even in patients who had improved LV function or NYHA

TABLE 4.1 Primary Prevention ICD at Initial Implant

Indication	Appropriate Use Score (1-9)	
No Clinically Relevant Ventricular Arrhythmias on ICD Since Implant		
157. ■ Patient received primary prevention ICD when LVEF was ≤35% ■ LVEF now unchanged	A (8)	
158. ■ Patient received primary prevention ICD when LVEF was ≤35% ■ LVEF now 36%-49%	M (6)	
159. ■ Patient received primary prevention ICD when LVEF was ≤35% ■ LVEF now ≥50% (normalized)	M (4)	
No Clinically Relevant Ventricular Arrhythmias on ICD Since Implant (Now Has Prognosis <1 Year)	**Replace with ICD**	**Replace with Pacemaker***
160. ■ Patient received primary prevention ICD ■ Pacemaker dependent	M (4)	A (8)
161. ■ Patient received primary prevention ICD ■ No pacing indication	R (2)	R (2)
Clinically Relevant Ventricular Arrhythmias on ICD Since Implant	**Appropriate Use Score**	
162. ■ Patient received primary prevention ICD when LVEF was ≤35% ■ LVEF now unchanged	A (9)	
163. ■ Patient received primary prevention ICD when LVEF was ≤35% ■ LVEF now 36%-49%	A (8)	
164. ■ Patient received primary prevention ICD when LVEF was ≤35% ■ LVEF now ≥50% (normalized)	A (7)	
165. ■ Patient received primary prevention ICD ■ Now has prognosis <1 year	M (5)	

*"Replace device with 1 that has pacing therapy only." This assumes that no additional hardware is required to perform the replacement.

A = Appropriate; ICD = implantable cardioverter-defibrillator; LVEF = left ventricular ejection fraction; M = May Be Appropriate; R = Rarely Appropriate.

functional class beyond guideline recommendations for primary prevention ICD implantation, leading authors to conclude that defibrillator protection remained justifiable.[107] Some degree of arrhythmic risk also remained in a population of CRT super-responders.[108]

TABLE 4.2 Secondary Prevention ICD at Initial Implant

Indication	Appropriate Use Score (1-9)
166. ■ Patient received secondary prevention ICD ■ No ventricular arrhythmia since initial implant	A (8)
167. ■ Patient received secondary prevention ICD ■ Had ventricular tachyarrhythmias in the monitor zone lasting >30 seconds, but no treated ventricular arrhythmias since initial implant	A (8)
168. ■ Patient received secondary prevention ICD ■ Had ventricular arrhythmias receiving ICD therapy since implant	A (9)

A = Appropriate; ICD = implantable cardioverter-defibrillator.

TABLE 4.3 Primary Prevention at Initial Implant: Replacement of CRT-ICD for ERI

Indication	Appropriate Use Score (1-9)	
	Replace With CRT-ICD	**Replace With CRT- Pacemaker**
169. ■ Patient received a CRT-ICD when LVEF was ≤35% ■ LVEF now unchanged (despite clinical improvement)	A (9)	R (3)
170. ■ Patient received a CRT-ICD when LVEF was ≤35% ■ LVEF now 36%-49%	A (8)	M (6)
171. ■ Patient received a CRT-ICD when LVEF was ≤35% ■ LVEF now ≥50% (normalized)	A (7)	M (6)

A = Appropriate; CRT = cardiac resynchronization therapy; ERI = elective replacement indicator; ICD = implantable cardioverter-defibrillator; LVEF = left ventricular ejection fraction; M = May Be Appropriate; R = Rarely Appropriate.

Section 4 Results and Discussion

Following initial CIED implantation, clinical situations evolve and previously present conditions that merited ICD or CRT implantation may change. In addition to changes in HF status, pacing frequency, or clinical arrhythmia events treated by the ICD, concomitant medical illnesses may also evolve, so that considerations may include replacement of the pulse generator and potentially changing the type of device (eg, from an ICD to a PM). For example, in a PM-dependent patient who develops cancer with an anticipated life expectancy of <1 year, consideration may be given to changing the ICD to a PM. In addition, the clinical evidence for CIED placement

TABLE 4.4 Secondary Prevention at Initial Implant: Replacement of CRT-ICD for ERI

Indication	Appropriate Use Score (1-9)	
	Replace With CRT-ICD	**Replace With CRT- Pacemaker***
172. ■ Patient received a CRT-ICD when LVEF was ≤35% ■ LVEF now unchanged (despite clinical improvement)	A (9)	
173. ■ Patient received a CRT-ICD when LVEF was ≤35% ■ LVEF now 36%-49%	A (9)	R (3)
174. ■ Patient received a CRT-ICD when LVEF was ≤35% ■ LVEF now ≥50% (normalized)	A (7)	M (5)

NOTE: grey shaded box indicates "not rated."

*"Replace device with 1 that has CRT pacing therapies only." This assumes that no additional hardware is required to perform the replacement. If additional hardware would be required, then this option could still be chosen with the plan to replace with an ICD but turn off tachycardia therapy functions.

A = Appropriate; CRT = cardiac resynchronization therapy; ERI = elective replacement indicator; ICD = implantable cardioverter-defibrillator; LVEF = left ventricular ejection fraction; M = May Be Appropriate; R = Rarely Appropriate.

may evolve across time with ongoing availability of new trial data.

Once patients have received appropriate ICD therapy for ventricular arrhythmias, they are subsequently considered "secondary prevention" at the time of generator replacement in the NCDR, although it is recognized that some of these arrhythmias may have spontaneously terminated without hemodynamically significant symptoms if an ICD was not in place. There is currently a paucity of data related to generator replacement in patients who received primary prevention ICDs but have not experienced clinically relevant arrhythmias since initial implantation, and generator replacement is often still performed regardless of LVEF at follow-up. There is some evidence to suggest that patients who have improvement in LV function without appropriate therapy following initial ICD implantation may still be at risk for subsequent appropriate therapy following ICD generator replacement[109,110]; however, the decision to perform a generator replacement or consider "upgrade" of a device is not without risk. Therefore, the scenarios in this document seek to assess appropriateness for a variety of clinical situations related to either "replace the pre-existing CIED" or "downgrade" ICDs or CRT-ICDs to PMs. This is an area where gaps in evidence still exist with the need for additional trials to better understand who should undergo generator replacement.

Scenarios that consider original indication for the device, life expectancy, or LVEF recovery are described in **Tables 4.1 to 4.4**. In patients who had ICDs originally implanted for primary prevention without clinically relevant ventricular arrhythmias since implant, with LVEF remaining ≤35%, replacement with an ICD was considered Appropriate, whereas in patients with improvement in EF (>35%), replacement was considered May Be Appropriate (**Table 4.1**). For patients who experience clinically relevant ventricular arrhythmias after implantation of a primary prevention ICD, replacement of the ICD was considered Appropriate regardless of whether LVEF improved at the time of replacement (**Table 4.1**).

Replacement of a CRT-ICD with a CRT PM when the LVEF had improved since initial device implantation for primary prevention indications was rated as May Be Appropriate (**Table 4.3**). These ratings of May Be Appropriate are consistent with the gaps of knowledge in this area, as there is a paucity of data examining sudden death risk following some recovery of LV function.

Section 5: Dual-Chamber ICD (as Opposed to Single-Chamber ICD) for Patients Who Meet Criteria for ICD Implantation (but No CRT Indication)

Assumptions and Considerations

- In this section, symptoms refer to those potentially related to bradycardia, such as lightheadedness, presyncope, loss of consciousness, fatigue, or reduced exercise tolerance.
- All listed scenarios are asymptomatic unless otherwise specified.
- For scenarios where the QRS is wide, it is assumed that the patient does not otherwise meet criteria for CRT implantation.
- This section refers to dual-chamber ICDs (ie, atrial and ventricular leads) but does not address any specific position of the ventricular lead, because physiological pacing options are discussed in a separate section.
- As this section refers to initial ICD implantation, it is assumed that the latest technology device is available. This includes single-chamber devices that have availability of algorithms to detect AF, even in the absence of a separately implanted atrial lead (this may include algorithms that detect AF via irregular R-R intervals with only a single ICD lead positioned in the RV or a totally subcutaneous ICD system, as well as an ICD system that has a separate sensing bipole in the atrium on the ICD lead, ie, VDD system).

Supraventricular tachyarrhythmias are the most common cause of inappropriate shock delivery for TV-ICD systems. Inappropriate shocks can lead to pain, proarrhythmia, and a reduced QOL. The purpose of detection enhancements is to help discriminate supraventricular tachycardia (SVT) from VT, selectively rejecting SVT that has a rate overlapping with programmed rates in the VT zone to avoid inappropriate ICD therapy. As dual-chamber ICDs can analyze the relationship between the atrial and ventricular electrograms, it has been hypothesized that dual-chamber ICDs may be superior to single-chamber devices in distinguishing supraventricular from ventricular arrhythmias, thus anticipating a reduction in inappropriate therapies. However, nonrandomized studies, a registry, and a small early randomized study failed to demonstrate benefit of dual-chamber devices vs single-chamber devices in improving arrhythmia detection and reducing inappropriate therapies.[111-116] When examining secondary prevention ICD studies that evaluate outcomes of patients with dual- vs single-chamber ICDs, a meta-analysis of 9 studies also showed a similar rate of inappropriate detection of SVT and inappropriate therapy.[24] In contrast, a nationwide multicenter registry of primary prevention ICD patients in Spain showed that dual-chamber devices were associated with a lower risk of inappropriate shocks compared with that of single-chamber ICDs.[117]

With improvements in atrial sensing and the addition of morphology-based algorithms for detection enhancement in dual-chamber devices, subsequent prospective investigation was performed. A larger randomized study demonstrated that dual-chamber devices, programmed to

optimize detection enhancements and minimize ventricular pacing, significantly reduced inappropriate ICD detections (odds ratio: 0.53; 95% CI: 0.3-0.94; $P = 0.03$).[118] Although there was a reduction in inappropriate therapy delivery (ATP or shock) in the dual-chamber group, the odds of an inappropriate shock were not significantly different between single- and dual-chamber groups.[118] However, dual-chamber devices have been associated with an increased rate of periprocedural complications, including pneumothorax, hematoma, and lead dislodgment.[25,111] In a large cohort of patients (N = 104,049) in the NCDR ICD Registry, dual-chamber devices were associated with an increased rate of in-hospital periprocedural complications (odds ratio: 1.40; 95% CI: 1.28-1.52; $P < 0.001$) and in-hospital mortality (odds ratio: 1.45; 95% CI: 1.2-1.74; $P < 0.001$) compared with that of single-chamber ICDs.[25] Higher rates for pulse generator replacements during follow-up were also seen with dual-chamber devices.[111]

Controversy persists as to whether potential benefits of dual-chamber ICDs outweigh additional risks in patients who do not require dual-chamber bradycardia pacing. Although there is some evidence in favor of and more evidence against implanting an atrial lead for tachycardia discrimination to decrease the rate of inappropriate therapy, implantation of an atrial lead for this indication is not encouraged. Instead, particular attention to evidence-based programming, such as that performed in the MADIT-RIT (Multicenter Automatic Defibrillator Implantation Trial-Reduce Inappropriate Therapy) trial and recommended by the "2015 HRS/EHRA/APHRS/SOLAECE Expert Consensus Statement on Optimal Implantable Cardioverter-Defibrillator Programming and Testing," is recommended to reduce unnecessary ICD therapies.[16]

Tables 5.1 to 5.4 describe scenarios where dual-chamber devices may be considered, modified by the presence or absence of underlying conduction system disease, atrial arrhythmias, or specific genetic syndromes.

Section 5 Results and Discussion

Clinical trials evaluating the mortality benefit of ICD therapy for primary or secondary prevention have mostly involved implantation of single-chamber devices. There has been marked variation in single- vs dual-chamber ICD usage in the United States, as demonstrated by reports from the NCDR ICD Registry.[119,120] While institutional variation persists, use of dual-chamber devices in patients without a clear clinical indication for an atrial lead has decreased with time.[120] The potential benefit of single- vs dual-chamber PM implantation was previously addressed in a consensus document initiated by HRS,[22] but additional considerations may apply to ICD therapy. The decision to implant a dual-chamber ICD, rather than a single-chamber ICD, may include a variety of clinical

TABLE 5.1 No Conduction Abnormalities

	Indication	Appropriate Use Score (1-9)
Meets Criteria for ICD (Narrow QRS <120 ms)		
175.	■ Sinus rhythm with normal PR interval ■ Asymptomatic	M (4)

ICD = implantable cardioverter-defibrillator; M = May Be Appropriate.

TABLE 5.2 Conduction System Abnormalities

	Indication	Appropriate Use Score (1-9)
Conduction System Abnormalities Patient With Sinus Node Dysfunction Who Meets Criteria for ICD		
176.	■ Sinus node dysfunction (includes sinus pauses, chronotropic incompetence, or marked sinus bradycardia that results from drug therapy required to treat other conditions) ■ Symptomatic	A (9)
177.	■ Resting sinus bradycardia (resting heart rate <50 beats/min) ■ Asymptomatic	A (7)
Conduction System Abnormalities Patient With AV Conduction Disease Who Meets Criteria for ICD (Narrow QRS <120 ms)		
178.	■ Third-degree AV block or advanced second-degree AV block (Mobitz type II AV block or high-degree AV block) ■ Symptomatic ■ CRT not indicated	A (9)
179.	■ Third-degree AV block or advanced second-degree AV block (Mobitz type II AV block or high-degree AV block) ■ Asymptomatic ■ CRT not indicated	A (8)
180.	■ Mobitz type I AV block ■ Asymptomatic ■ CRT not indicated	M (6)
181.	■ First-degree AV block (PR 200-300 ms) ■ Asymptomatic	M (5)
182.	■ First-degree AV block (PR >300 ms) ■ Asymptomatic	M (6)

	Conduction System Abnormalities Acute MI or Ischemic Event Who Meets Criteria for ICD	Narrow QRS (<120 ms)	Chronic Wide QRS (≥120 ms)
183.	■ Transient second-degree Mobitz type II or third-degree AV block thought to be secondary to ischemia ■ Status postsuccessful revascularization	M (4)	M (5)
184.	■ Transient second-degree Mobitz type II or third-degree AV block thought to be secondary to ischemia ■ Not amenable to revascularization	M (6)	M (6)

Conduction System Abnormalities Cardiac Valve Surgery Who Meets Criteria for ICD		
185.	■ Transient AV block ■ Narrow QRS (<120 ms)	M (5)
186.	■ New LBBB and first-degree AV block ■ LVEF >50%	M (6)

A = Appropriate; AV = atrioventricular; bpm = beats per minute; CRT = cardiac resynchronization therapy; ICD = implantable cardioverter-defibrillator; LBBB = left bundle branch block; M = May Be Appropriate; MI = myocardial infarction; R = Rarely Appropriate.

TABLE 5.3 Tachyarrhythmias

	Indication	Appropriate Use Score (1-9)
Atrial Arrhythmias or "SVT" and "No Standard Pacing Indications"*		
187.	■ Paroxysmal atrial arrhythmias	M (6)
188.	■ Underlying structural heart disease (eg, ischemic or nonischemic CM) ■ No known paroxysmal atrial arrhythmias or SVT	M (4)
189.	■ Structurally normal heart ■ No known paroxysmal atrial arrhythmias or SVT	R (3)
190.	■ Long-standing persistent or permanent atrial fibrillation or atrial flutter ■ No plans for cardioversion or rhythm control	R (2)
Known Slow Ventricular Arrhythmias		
191.	■ Physically active patient ■ Known "slow VT" that overlaps with sinus tachycardia rate	M (6)

*Use of dual-chamber device for theoretical benefit related to arrhythmia discrimination (SVT vs VT detection enhancements).

CM = cardiomyopathy; M = May Be Appropriate; R = Rarely Appropriate; SVT = supraventricular tachycardia; VT = ventricular tachycardia.

considerations, such as the potential need for pacing due to underlying conduction system disease, potential impact of drugs on sinus or AV conduction, potential suppression of ventricular arrhythmias with atrial pacing in specific disorders, or relative value of device algorithms in arrhythmia discrimination.

Scenarios evaluating the need for dual-chamber ICDs are described in Tables 5.1 to 5.4. These scenarios are modified based on concomitant conduction system disease or pacing indications, coexisting atrial arrhythmias with plans for rhythm vs rate control, known slow ventricular arrhythmias, or other disorders (congenital long QT syndrome or hypertrophic CM). For scenarios where the QRS was wide, the panel was instructed to assume that the patient does not otherwise meet criteria for CRT implantation.

TABLE 5.4 Other Disorders

	Indication	Appropriate Use Score (1-9)
Genetic Disorders*		
192.	■ Congenital Long QT syndrome ■ ICD for secondary prevention	M (6)
193.	■ Congenital Long QT syndrome ■ ICD for primary prevention	M (6)
194.	■ Hypertrophic cardiomyopathy ■ Narrow QRS (<120 ms) ■ No standard bradycardia pacing indications	M (5)
195.	■ Hypertrophic cardiomyopathy ■ Wide QRS (≥120 ms) ■ No standard bradycardia pacing indications	M (6)

*Use of dual-chamber device for theoretical benefit related to arrhythmia discrimination (SVT vs VT detection enhancements) and pacing to reduce the development of ventricular arrhythmias.

ICD = implantable cardioverter-defibrillator; M = May Be Appropriate.

Dual-chamber ICD implantation was considered May Be Appropriate for congenital long QT syndrome and hypertrophic CM (Table 5.4). Although atrial pacing could potentially reduce risk for ventricular arrhythmias in some patients with congenital long QT syndrome, this highlights flexibility and importance of considering individual patient situations, as the atrial lead may not be necessary and single-chamber devices may be preferable in some situations.

Implantation of a dual-chamber device was considered Appropriate for patients with standard pacing indications, including symptomatic sick sinus syndrome with chronotropic incompetence or marked sinus bradycardia that results from drug therapy required to treat other conditions and third-degree AV block or advanced second-degree AV block (Mobitz type II AV block or high-degree AV block) (Table 5.2). Implantation of a dual-chamber device was also considered Appropriate in scenarios that would not necessarily meet standard guidelines for PM implantation (eg, in the setting of asymptomatic sinus bradycardia) (Table 5.2); however, in contrast with the 2013 AUC document, history of paroxysmal atrial arrhythmias or slow ventricular arrhythmias where "slow VT" overlaps with the sinus tachycardia rate) (Table 5.3) is now considered May Be Appropriate (previously considered Appropriate). This is consistent with evolving evidence from more recent studies related to previously perceived benefits related to arrhythmia discrimination or detection of "silent" atrial arrhythmias with insertion of an atrial lead. The only 2 clinical situations in which implantation of a dual-chamber device was rated as Rarely Appropriate were in the setting of long-standing persistent or permanent AF or flutter in patients in whom cardioversion or rhythm control strategies are not planned and in patients with structurally normal hearts without known paroxysmal atrial arrhythmias or SVT (Table 5.3). All other clinical scenarios were rated as May Be Appropriate (Tables 5.1 to 5.4). These scenarios highlight differences between the thresholds for implanting a standalone permanent PM compared with inserting an atrial lead in a patient undergoing ICD implantation.

Section 6: Totally Subcutaneous ICD

Assumptions and Considerations

- It is assumed that all patients considered for subcutaneous implantable cardioverter-defibrillator (S-ICD) implantation already meet standard indications for ICD implantation.
- As currently available technology does not include standard bradycardia backup pacing or CRT, it is assumed that patients considered for S-ICD implantation do not have bradycardia or CRT pacing indications,

unless a previously implanted PM is already present. If a pre-existing PM is present, it is assumed that standard testing will be performed at implantation to exclude potential PM-ICD interactions.

- For secondary prevention indications, it is assumed that frequent ATP is not needed for treatment of frequent MMVT (as this is noted in the FDA labeling of this device).
- All indications assume patients have met appropriate screening for implantation with criteria met in ≥1 of 3 leads in 2 different postures (eg, supine and sitting or standing). Additional screening may be appropriate for some disease processes (eg, hypertrophic CM), such as stress testing, to exclude T-wave oversensing.

The ICD lead has been considered the "weakest link" or most fragile component of the ICD system, with an increased rate of lead failure over time.[121,122] Transvenous leads are also associated with acute implantation risks, such as pneumothorax, perforation, or lead dislodgment. The S-ICD system was developed with the intent of reducing acute and long-term complications related to ICD systems. For example, younger patients are at increased risk for long-term lead failure and may require multiple lead replacements throughout their lifetime. This subcutaneous system does not require electrodes "in" or "on" the heart and can be placed strictly by anatomical landmarks without a need for fluoroscopy. The lead has no central lumen and is not subject to flexing or motion with each cardiac cycle, the latter of which can lead to lead fatigue or stress, resulting in lead failure over time.

The S-ICD system was approved by the FDA in 2012 after completion of the IDE (Investigational Device Exemption) study in the United States.[123] It is indicated for use in patients who meet current ICD indications and is intended to "provide defibrillation therapy for the treatment of life-threatening ventricular tachyarrhythmias in patients who do not have symptomatic bradycardia, incessant VT, or spontaneous, frequently recurring VT that is reliably terminated with antitachycardia pacing." Although the IDE study excluded patients with renal failure, data from the NCDR demonstrate that 20% of patients who receive the S-ICD in the United States are on dialysis.[124] The 2017 AHA/ACC/HRS Guideline for Management of Patients With Ventricular Arrhythmias and the Prevention of Sudden Cardiac Death recommends that "patients who meet criteria for an ICD who have inadequate vascular access or are at high risk for infection, and in whom pacing for bradycardia or VT termination or as part of CRT is neither needed nor anticipated, a subcutaneous implantable cardioverter-defibrillator is recommended," and this is a Class I recommendation (Level of Evidence [LOE] B-nonrandomized [NR]).[4] The choice for an S-ICD is reasonable, as long as pacing (for bradycardia, VT termination, CRT) is neither needed nor anticipated (Class IIa, LOE B-NR), while recommendations clearly state that an S-ICD should not be implanted and can cause harm if there is an indication for bradycardia pacing, CRT, or if antitachycardia pacing for VT termination is required (Class III: Harm, LOE B-NR).[4]

The S-ICD has been utilized in a broad range of cardiac diseases and in patients with multiple comorbidities. In a postmarket registry (EFFORTLESS [Evaluation oF FactORs ImpacTing CLinical Outcome and Cost EffectiveneSS of the S-ICD]) examining 985 patients, 29% had ischemic CM, 8% nonischemic dilated CM, 11% hypertrophic CM, and 20% inherited channelopathies.[125] In the IDE study, 70% of patients had LVEF ≤35% with a mean LVEF 36 ± 16%.[123] In the NCDR examining 3,717 implants in the United States, 74% had HF (NYHA functional class II-IV), 20% had atrial arrhythmias, 40% had prior MI, and 20% were on dialysis.[124]

Longer-term outcomes in patients receiving S-ICD therapy have been examined. In the combined EFFORTLESS Registry and IDE S-ICD data, no electrode failures and no S-ICD-related endocarditis or bacteremia were noted in 882 patients with a follow-up of 651 ± 345 days.[126] Data from a real-world European registry demonstrated a low lead fracture rate of 0.3% after a median follow-up of 23 months.[127] Until recently, no randomized data were available comparing outcomes of patients with S-ICDs with those with transvenous systems. A meta-analysis of 5 case-control studies showed that lead complications were lower with the S-ICD than with transvenous systems, while infection and system failure were similar.[128] Total inappropriate therapies were similar between S-ICD and transvenous systems, while the reason for inappropriate therapy was more likely due to SVT with transvenous systems and more likely due to T-wave oversensing with the S-ICD.[128] The ATLAS (Avoid Transvenous Leads in Appropriate Subjects) study investigated ICD performance related to the delivery of ICD therapy by S-ICDs vs transvenous systems. The study population included 544 patients who were followed for a mean of 2.5 years. There was a 90% decrease in perioperative, lead-related complications without significantly compromising the effectiveness of ICD shocks, although there was more early postoperative pain and a trend for more inappropriate shocks.[129]

The PRAETORIAN (Prospective, RAndomizEd comparison of subcuTaneOus and tRansvenous ImplANtable cardioverter-defibrillator therapy) trial was recently published and provides a direct comparison between the S-ICD and transvenous systems. This trial randomized

849 patients without pacing indications to the S-ICD vs TV-ICD with a primary composite endpoint of device-related complications and inappropriate shocks. The S-ICD was noninferior to TV-ICD with respect to device-related complications and inappropriate shocks.[130]

The UNTOUCHED (UNdersTanding OUtComes With tHe S-ICD in Primary Prevention Patients With Low Ejection Fraction) study characterized performance of S-ICD in primary prevention patients with LVEF ≤35%, and final results were recently published.[131,132] This was a single-arm study of the S-ICD implanted for primary prevention (ischemic or nonischemic CM, LVEF ≤35%) without pacing indications. The primary outcome was inappropriate shock-free rate, demonstrating a freedom from inappropriate shocks of 95.9% at 18 months, meeting the performance goal derived from results in the MADIT-RIT study.[132] This study also demonstrated a high efficacy and safety of the S-ICD, despite the relatively high incidence of comorbidities in comparison with earlier S-ICD trials, with an arrhythmia conversion success rate of 98.4% and complication-free rate of 92.7% at 18 months.[132]

The S-ICD accounts for only a small percentage of ICDs implanted in the United States, representing 3.8% of all ICDs implanted according to the NCDR data from the fourth quarter of 2020 (data available June 30, 2021).[101] The S-ICD appears to be favored in those with prior transvenous infection, at high risk for infection, and with poor vascular access, as well as in younger patients. Reasons for the slow uptake of this device may be multifactorial, but the lack of availability of bradycardia or antitachycardia pacing in currently approved devices likely plays a role. Technology including a leadless PM combined with the S-ICD is currently being investigated with initial results of the MODULAR ATP (Effectiveness of the EMPOWER™ Modular Pacing System and EMBLEM™ Subcutaneous ICD to Communicate Antitachycardia Pacing) study recently published.[133]

Tables 6.1 to 6.3 describe scenarios where the S-ICD may be considered for primary or secondary prevention indications.

Section 6 Results and Discussion

While original studies evaluating the S-ICD for primary and secondary prevention indications excluded patients with renal failure, real-world clinical experience demonstrates that the S-ICD was frequently implanted in patient in patients on dialysis or other niche indications, such as those at high risk for endovascular infection. In the NCDR ICD Registry, 20% of patients with an S-ICD were on dialysis, 16% had a prior PM or ICD implanted, and 8% were implanted with an indication listed as channelopathy.[109] Although mean EF was 36% and 70% of patients had EF ≤35% in the original IDE trial and 58% of primary prevention patients had EF ≤35% in the EFFORTLESS Registry,[125] there appeared to be slow uptake in use of the S-ICD for standard primary prevention indications in the United States. More recent investigation focusing on standard primary prevention indications in the UNTOUCHED trial, where 100% of patients had EF ≤35%, demonstrated the high efficacy and safety of the S-ICD despite the relatively high incidence of comorbidities in comparison with that of earlier S-ICD trials.[132]

The S-ICD was considered Appropriate for multiple primary prevention scenarios, with or without multiple comorbidities (Table 6.1). The S-ICD was also considered

TABLE 6.1 Primary Prevention

Indication	Appropriate Use Score (1-9)
Primary Prevention*	
196. ■ Ischemic CM, LVEF ≤35%	A (7)
197. ■ Nonischemic CM, LVEF ≤35%	A (7)
198. ■ Hypertrophic CM	A (7)
199. ■ Congenital heart disease	A (7)
Primary Prevention, LVEF ≤35% With Comorbidities	
200. ■ ESRD on dialysis	A (7)
201. ■ CKD, not yet on dialysis	A (7)
202. ■ Prior endovascular infection or prior lead extraction for infection, infection resolved	A (7)
203. ■ Unresolved infection associated with risk for hematogenous seeding	A (7)
204. ■ IV substance use disorder (ongoing)	M (4)
205. ■ Patient factors that increase risk for infection, eg, immunocompromised, cancer with anticipated longevity >1 year	A (7)
206. ■ Venous access issues/venous obstruction	A (8)

*Patient otherwise meets indications for primary prevention ICD.

A = Appropriate; CKD = chronic kidney disease; CM = cardiomyopathy; ESRD = end-stage renal disease; IV = intravenous; LVEF = left ventricular ejection fraction; M = May Be Appropriate.

TABLE 6.2.1 Secondary Prevention (Sustained Ventricular Arrhythmia)

Indication	Appropriate Use Score (1-9)
Secondary Prevention, VF/PMVT (Sustained)	
207. ■ Ischemic CM, LVEF ≤35%	A (7)
208. ■ Nonischemic CM, LVEF ≤35%	A (7)
209. ■ Hypertrophic CM	A (7)
210. ■ Congenital heart disease	A (7)
Secondary Prevention, Sustained MMVT	
211. ■ Single-episode MMVT	M (5)
212. ■ Recurrent MMVT	M (4)

A = Appropriate; CM = cardiomyopathy; LVEF = left ventricular ejection fraction; M = May Be Appropriate; MMVT = monomorphic ventricular tachycardia; PMVT = polymorphic ventricular tachycardia; VF = ventricular fibrillation.

TABLE 6.2.2 Secondary Prevention (Syncope Felt to Be Due to Ventricular Arrhythmia)

Unexplained Syncope, No Structural Heart Disease (Inherited Arrhythmia Syndromes — Genetic Channelopathy)		
213.	■ Long QT syndrome	M (6)
214.	■ Brugada ECG	A (7)
215.	■ Catecholaminergic PMVT	A (7)
Unexplained Syncope, With Structural Heart Disease (Inherited Arrhythmia Syndromes — Arrhythmogenic Cardiomyopathy)		
216.	■ Sarcoidosis*	M (5)
217.	■ RV cardiomyopathy	A (7)
218.	■ Cardiac amyloid	M (5)

*Without current pacing indication, as noted in assumptions.

A = Appropriate; ECG = electrocardiogram; M = May Be Appropriate; PMVT = polymorphic ventricular tachycardia; RV = right ventricular.

Appropriate for secondary prevention in the setting of sustained PMVT/VF and May Be Appropriate for sustained MMVT (Table 6.2.1). The absence of antitachycardia pacing capability limits the type of therapy for MMVT, likely accounting for the appropriateness of the S-ICD in these scenarios, although this could change if a combination of leadless pacing is approved for use with the S-ICD. The S-ICD was also considered Appropriate for syncope in the setting of Brugada syndrome and catecholaminergic PMVT, likely because arrhythmias associated with these syndromes are not likely to be pace-terminable. On the other hand, the S-ICD was considered May Be Appropriate for patients with unexplained syncope and structural heart disease with inherited arrhythmia syndromes (sarcoidosis and amyloid) in patients who do not have a pacing indication at the time of initial implantation (Table 6.2.2). This level of appropriateness may be due to concerns of pacing indications subsequently developing in situations where infiltrative CM is present.

TABLE 6.3 Primary or Secondary Prevention

Indication		Appropriate Use Score (1-9)
Primary or Secondary Prevention, Special Situation		
219.	■ Athletic patient	M (6)
Syncope		
220.	■ Syncope with inducible sustained MMVT	M (5)
Primary or Secondary Prevention, Concomitant Atrial Arrhythmias		
221.	■ Paroxysmal atrial arrhythmias	M (5)
222.	■ Persistent or permanent atrial arrhythmias	A (7)

A = Appropriate; M = May Be Appropriate; MMVT = monomorphic ventricular tachycardia.

Section 7: HF: CRT—No Prior Implant

Assumptions and Considerations

- ECG criteria for LBBB, RBBB, and IVCD are accurately determined.
- Non-LBBB is defined as RBBB or nonspecific intraventricular conduction block (not transient or rate-related).
- QRS duration is accurately measured.
- LVEF is accurately measured.
- All assessments are made after ≥3 months of optimized GDMT.
- If persistent AF is present, it should be assumed that CRT pacing can be maximized with a high percentage of pacing (≥98%) to optimize CRT delivery.

The 2013 HF guidelines set standards for the use of CRT in HF,[13] and the 2017 update did not change the basic recommendations.[12] Importantly, patients with LBBB, wider QRS durations, and female sex derive the greatest benefit from CRT. Benefit for patients with RBBB and IVCDs is less certain and may be detrimental.[134] Newer therapies, including HBP and left bundle branch area pacing (LBBAP), may address the needs of these patients. The strongest recommendations (Class I) for CRT are for patients who have LVEF ≤35%, sinus rhythm, LBBB with a QRS ≥150 ms, and NYHA functional class II, III, or ambulatory IV symptoms on GDMT. Less strong recommendations (Class IIa) are for patients who have the following: 1) LVEF ≤35%, sinus rhythm, a non-LBBB pattern with QRS ≥150 ms, and NYHA functional class III/ambulatory class IV symptoms on GDMT; 2) LVEF ≤35%, sinus rhythm, LBBB with a QRS 120 to 149 ms, and NYHA functional class II, III, or ambulatory IV symptoms on GDMT; 3) AF and LVEF ≤35% on GDMT if a) the patient requires ventricular pacing or otherwise meets CRT criteria, and b) AV nodal ablation or rate control allows near 100% ventricular pacing with CRT; and 4) are on GDMT, have LVEF ≤35%, and are undergoing new or replacement device implantation with anticipated ventricular pacing (>40%).[135] Further, even less strong recommendations (Class IIb) are for patients who have the following: 1) LVEF ≤35%, sinus rhythm, a non-LBBB pattern with a QRS duration of 120 to 149 ms, and NYHA functional class III/ambulatory class IV symptoms on GDMT; 2) LVEF ≤35%, sinus rhythm, a non-LBBB pattern with QRS ≥150 ms, and NYHA functional class II symptoms on GDMT; and 3) LVEF ≤30%, ischemic etiology of HF, sinus rhythm, LBBB with QRS ≥150 ms, and NYHA functional class I symptoms on GDMT. CRT is not recommended (Class III, no benefit) for the following patients: 1) those with NYHA functional class I or II symptoms and non-LBBB pattern with QRS <150 ms; and 2) those whose comorbidities and/or frailty limit survival to <1 year.[135]

The 2018 bradycardia pacing guidelines add additional applications of CRT to treat or prevent HF, all Class II.[7] Line items include the following:

- In patients with AV block who have an indication for permanent pacing with an LVEF between 36% and 50% and are expected to require ventricular pacing >40% of the time, it is reasonable to choose pacing methods that maintain physiological ventricular activation (eg, CRT or HBP) vs RV pacing.
- In patients with AV block who have an indication for permanent pacing with an LVEF between 36% and 50% and are expected to require ventricular pacing <40% of the time, it is reasonable to choose right ventricular pacing vs pacing methods that maintain physiological ventricular activation (eg, CRT or HBP).
- In patients with HF, a mildly to moderately reduced LVEF (36% to 50%), and LBBB (QRS ≥150 ms), CRT may be considered.

Although risk stratification has focused on the LV function as reflected by the LVEF, the RV may be arrhythmogenic if scar is present, whether it be the result of a primary myopathic process such as arrhythmogenic CM or infarction. For patients who survive RV MI, the long-term prognosis is primarily determined by the extent of LV involvement, but the risk for ventricular arrhythmia is present.[136] Thus, these patients warrant careful assessment of not only signs and symptoms of right heart dysfunction but also arrhythmia such as palpitations and syncope.

An area of research interest has been on the timing of implanting a CRT device in patients with new LBBB. In support of a 3-month waiting period before LVEF assessment for the candidacy for CRT are the multiple randomized clinical trials that mandated GDMT before implantation.[59,137] Furthermore, McNamara et al[138] have shown that 70% of individuals with recent-onset dilated CM have an increase of ≥10 LVEF units at 6 months, and 39% of ≥20 units; the LVEF normalized in 25%. Conversely, additional data suggest that early CRT might more rapidly improve LV function than with GDMT.[139,140]

Cardiac magnetic resonance imaging has gained prominence in risk stratification.[69] The presence of scar predicts appropriate ICD therapies and arrhythmic mortality.[141] Similarly, the response to CRT predicts arrhythmia outcome, such that responders have decreased arrhythmia risk compared with that of nonresponders.[142] Thus, while cardiac magnetic resonance imaging may become an ancillary tool to enhance risk stratification for the application of CRT and ICD therapy, a nonrandomized substudy of the DANISH (Danish Study to Assess the Efficacy of ICDs in Patients with Non-Ischemic Systolic Heart Failure on Mortality Implantable Cardioverter-Defibrillator) study showed that while LGE predicted all-cause mortality in patients with nonischemic systolic HF, ICDs did not extend survival in those individuals.

TABLE 7.1 Ischemic Cardiomyopathy

Indication		Appropriate Use Score (1-9)		
LVEF ≤30%, Ischemic Cardiomyopathy				
NYHA Functional Class		**I**	**II**	**III-amb IV**
223.	■ QRS <120 ms ■ Sinus rhythm	**R (1)**	**R (1)**	**R (1)**
224.	■ QRS 120-149 ms ■ LBBB ■ Sinus rhythm	**M (5)**	**A (7)**	**A (7)**
225.	■ QRS ≥150 ms ■ LBBB ■ Sinus rhythm	**A (7)**	**A (9)**	**A (9)**
226.	■ QRS 120-149 ms ■ Non-LBBB ■ Sinus rhythm	**R (3)**	**R (3)**	**M (6)**
227.	■ QRS ≥150 ms ■ Non-LBBB ■ Sinus rhythm	**M (4)**	**M (6)**	**A (7)**
LVEF 31%-35%, Ischemic Cardiomyopathy				
NYHA Functional Class		**I**	**II**	**III-amb IV**
228.	■ QRS <120 ms ■ Sinus rhythm	**R (1)**	**R (1)**	**R (1)**
229.	■ QRS 120-149 ms ■ LBBB ■ Sinus rhythm	**M (4)**	**A (7)**	**A (7)**
230.	■ QRS ≥150 ms ■ LBBB ■ Sinus rhythm	**A (7)**	**A (9)**	**A (9)**
231.	■ QRS 120-149 ms ■ Non-LBBB ■ Sinus rhythm	**R (3)**	**R (3)**	**M (6)**
232.	■ QRS ≥150 ms ■ Non-LBBB ■ Sinus rhythm	**M (4)**	**M (6)**	**A (7)**
LVEF ≤35%, Ischemic Cardiomyopathy, Persistent or Permanent Atrial Fibrillation				
QRS Duration (ms)			**120-149**	**≥150**
233.	■ LBBB ■ Persistent or permanent atrial fibrillation		**M (6)**	**A (7)**
234.	■ Non-LBBB ■ Persistent or permanent atrial fibrillation		**R (3)**	**M (6)**

A = Appropriate; amb = ambulatory; LBBB = left bundle branch block; LVEF = left ventricular ejection fraction; M = May Be Appropriate; NYHA = New York Heart Association; R = Rarely Appropriate.

Tables 7.1 to 7.7 and Figures 16 to 21 describe multiple scenarios where CRT may be considered, modified by various factors, including type of heart disease, NYHA functional class, LVEF, QRS duration, QRS morphology, concomitant atrial arrhythmias, duration of HF therapy, and timing after revascularization.

Section 7 Results and Discussion

CRT has emerged as a pillar in the armamentarium of treatment options for HF in patients with depressed LV function and QRS prolongation. It leads to reverse remodeling and a decrease in LV dimensions, a decrease

TABLE 7.2 Nonischemic Cardiomyopathy

Indication		Appropriate Use Score (1-9)		
LVEF ≤35%, Nonischemic Cardiomyopathy				
NYHA Functional Class		**I**	**II**	**III-amb IV**
235.	■ QRS <120 ms ■ Sinus rhythm	**R (1)**	**R (1)**	**R (1)**
236.	■ QRS 120-149 ms ■ LBBB ■ Sinus rhythm	**M (4)**	**A (7)**	**A (7)**
237.	■ QRS ≥150 ms ■ LBBB ■ Sinus rhythm	**A (7)**	**A (9)**	**A (9)**
238.	■ QRS 120-149 ms ■ Non-LBBB ■ Sinus rhythm	**R (3)**	**R (3)**	**M (6)**
239.	■ QRS ≥150 ms ■ Non-LBBB ■ Sinus rhythm	**M (4)**	**M (6)**	**A (7)**

LVEF ≤35%, Nonischemic Cardiomyopathy, Persistent or Permanent Atrial Fibrillation			
QRS Duration (ms)		**120-149**	**≥150**
240.	■ LBBB ■ Persistent or permanent atrial fibrillation	**M (6)**	**A (8)**
241.	■ Non-LBBB ■ Persistent or permanent atrial fibrillation	**M (4)**	**M (6)**

LVEF 31%-35%, Nonischemic Cardiomyopathy	**NYHA Functional Class**	**I**	**II**	**III-amb IV**
242.	■ QRS <120 ms ■ Sinus rhythm	**R (1)**	**R (1)**	**R (1)**
243.	■ QRS 120-149 ms ■ LBBB ■ Sinus rhythm	**M (4)**	**A (7)**	**A (7)**
244.	■ QRS ≥150 ms ■ LBBB ■ Sinus rhythm	**A (7)**	**A (9)**	**A (9)**
245.	■ QRS 120-149 ms ■ Non-LBBB ■ Sinus rhythm	**R (3)**	**R (3)**	**M (6)**
246.	■ QRS ≥150 ms ■ Non-LBBB ■ Sinus rhythm	**M (4)**	**M (6)**	**A (7)**

A = Appropriate; amb = ambulatory; LBBB = left bundle branch block; LVEF = left ventricular ejection fraction; M = May Be Appropriate; NYHA = New York Heart Association; R = Rarely Appropriate.

in mitral insufficiency, improved cardiac performance (both LV and RV function), a reduction in ventricular arrhythmias, and ultimately improved clinical outcomes, including lower NYHA functional class, decreased HF hospitalization, and improved survival.[2,143] Coupled with pharmacological GDMT, including beta-blockers, angiotensin-converting enzyme inhibitors, angiotensin receptor blockers, loop diuretics, and MRAs, the therapy is even more powerful. Furthermore, CRT has the capability to stabilize and forestall HF progression. Importantly, the survival benefit derived from CRT coupled with an ICD is sustained.[144]

TABLE 7.3 LVEF >35% to 50% of Any Etiology (ICD Indicated)

Indication		Appropriate Use Score (1-9)			
		Sinus Rhythm		**Persistent or Permanent Atrial Fibrillation**	
NYHA Functional Class		**I-II**	**III-amb IV**	**I-II**	**III-amb IV**
247.	■ QRS <120 ms	**R (1)**	**R (1)**	**R (1)**	**R (1)**
248.	■ QRS 120-149 ms ■ LBBB	**R (3)**	**M (4)**	**R (3)**	**M (4)**
249.	■ QRS ≥150 ms ■ LBBB	**M (4)**	**M (6)**	**M (4)**	**M (6)**
250.	■ QRS 120-149 ms ■ Non-LBBB	**R (2)**	**R (3)**	**R (3)**	**R (3)**
251.	■ QRS ≥150 ms ■ Non-LBBB	**R (3)**	**M (4)**	**R (3)**	**M (4)**

amb = ambulatory; ICD = implantable cardioverter-defibrillator; LBBB = left bundle branch block; LVEF = left ventricular ejection fraction; M = May Be Appropriate; NYHA = New York Heart Association; R = Rarely Appropriate.

The appropriateness of CRT in the previously scenarios outlined are in keeping with guideline recommendations. Regardless of etiology, ischemic or nonischemic, CRT for patients with a narrow QRS is not recommended (Table 7.1). With increasing QRS durations and when LBBB is present, the level of appropriateness for CRT incrementally increases (Tables 7.1 and 7.2). The recommendations are also modulated by the NYHA functional class level (less benefit when symptoms are less severe) and the presence of AF (less benefit). For patients with an LVEF

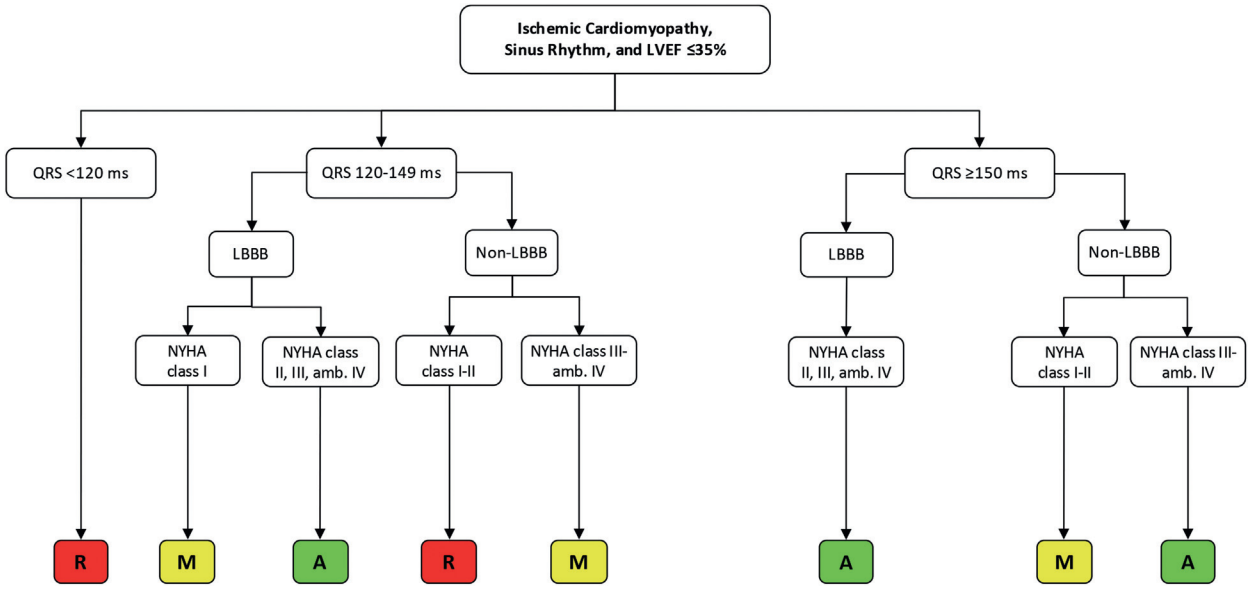
TABLE 7.4 LVEF ≤35% of Any Etiology

Indication		Appropriate Use Score (1-9)
NYHA Functional Class IV on Intravenous Inotropic Support		
252.	■ QRS 120-149 ms ■ LBBB ■ Sinus rhythm	**R (3)**
253.	■ QRS ≥150 ms ■ LBBB ■ Sinus rhythm	**M (6)**
254.	■ QRS 120-149 ms ■ Non-LBBB ■ Sinus rhythm	**R (3)**
255.	■ QRS ≥150 ms ■ Non-LBBB ■ Sinus rhythm	**R (3)**

NYHA Functional Class IV on Intravenous Inotropic Support		**QRS Duration 120-149 ms**	**QRS Duration ≥150 ms**
256.	■ LBBB ■ Atrial fibrillation	**R (3)**	**M (4)**
257.	■ Non-LBBB ■ Atrial fibrillation	**R (2)**	**R (3)**

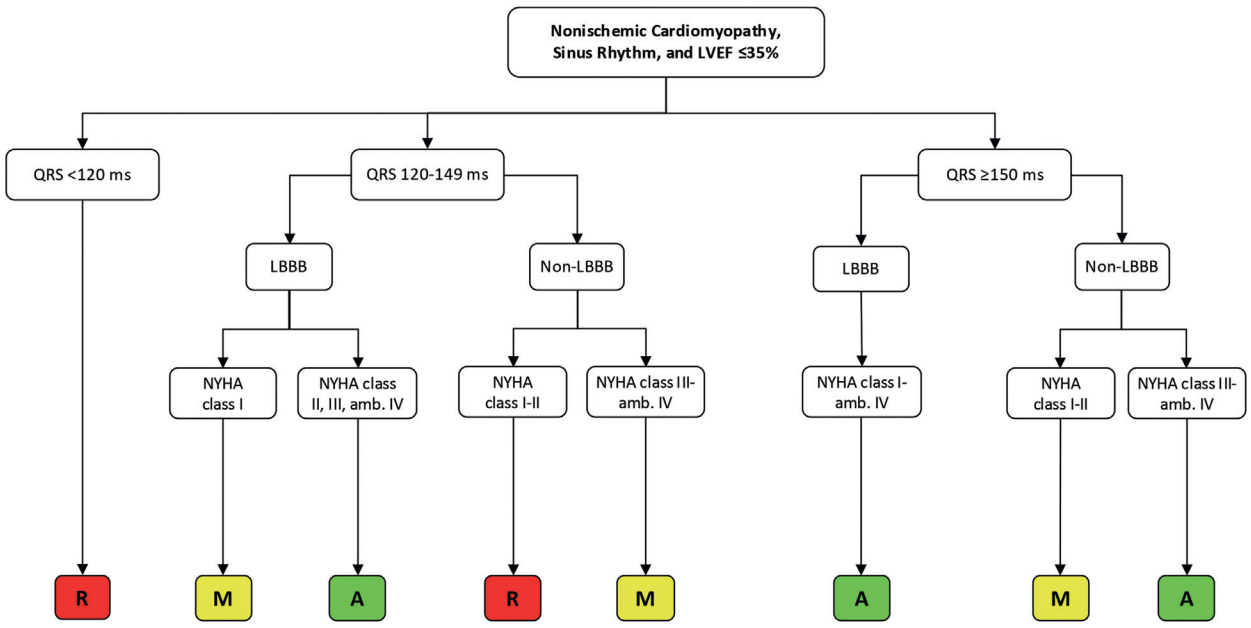
LBBB = left bundle branch block; LVEF = left ventricular ejection fraction; M = May Be Appropriate; NYHA = New York Heart Association; R = Rarely Appropriate.

FIGURE 16 **Summary of Table 7.1, CRT: Ischemic Cardiomyopathy**



A = Appropriate; amb = ambulatory; CRT = cardiac resynchronization therapy; LBBB = left bundle branch block; LVEF = left ventricular ejection fraction; M = May Be Appropriate; NYHA = New York Heart Association; R = Rarely Appropriate.

FIGURE 17 **Summary of Table 7.2, CRT: Nonischemic Cardiomyopathy**



A = Appropriate; amb = ambulatory; LBBB = left bundle branch block; LVEF = left ventricular ejection fraction; M = May Be Appropriate; NYHA = New York Heart Association; R = Rarely Appropriate.

TABLE 7.5 Pre-Existing or Anticipated RV Pacing With a Clinical Indication for ICD or Pacemaker Implantation

Indication		Appropriate Use Score (1-9)	
Intrinsic Narrow QRS, LVEF ≤35%			
NYHA Functional Class		**I-II**	**III-amb IV**
258.	■ RV pacing anticipated ≤40%	**M (4)**	**M (5)**
259.	■ RV pacing anticipated >40%	**A (7)**	**A (8)**
Intrinsic Narrow QRS, LVEF >35%			
NYHA Functional Class		**I-II**	**III-amb IV**
260.	■ RV pacing anticipated ≤40%	**R (2)**	**M (4)**
261.	■ RV pacing anticipated >40%	**M (5)**	**M (6)**

A = Appropriate; amb = ambulatory; ICD = implantable cardioverter-defibrillator; LVEF = left ventricular ejection fraction; M = May Be Appropriate; NYHA = New York Heart Association; R = Rarely Appropriate; RV= right ventricular.

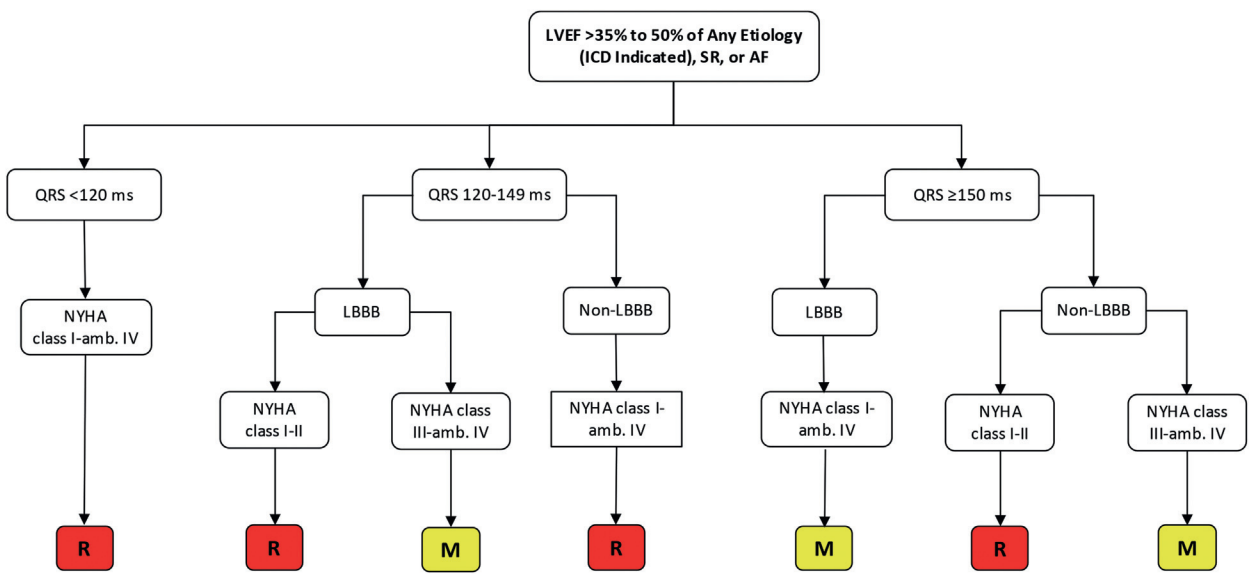
TABLE 7.6 Refractory Class III/IV HF <3 Months Post-revascularization (and Prior to 3 Months on Guideline-Directed Medical Therapy)

No Other Indication for Ventricular Pacing, LVEF ≤35%		
262.	■ QRS 120-149 ms ■ LBBB	**M (4)**
263.	■ QRS ≥150 ms ■ LBBB	**M (6)**
264.	■ QRS 120-149 ms ■ Non-LBBB	**R (3)**
265.	■ QRS ≥150 ms ■ Non-LBBB	**M (4)**
No Other Indication for Ventricular Pacing LVEF 36%-50%		
266.	■ QRS 120-149 ms ■ LBBB	**R (3)**
267.	■ QRS ≥150 ms ■ LBBB	**M (4)**
268.	■ QRS 120-149 ms ■ Non-LBBB	**R (2)**
269.	■ QRS ≥150 ms ■ Non-LBBB	**R (3)**

HF = heart failure; LBBB = left bundle branch block; LVEF = left ventricular ejection fraction; M = May Be Appropriate; R = Rarely Appropriate.

>35% to 50% of any etiology, CRT is either Rarely Appropriate (usually not advised given scores of R1) or sometimes Appropriate (but with reservation given scores of M4) (Table 7.3). Notably for patients with NYHA functional class IV HF on inotropic support, CRT is deemed May Be Appropriate only when there is LBBB and the QRS is ≥150 ms (Table 7.4). Similarly, when HF is NYHA functional class III or IV and refractory to pharmacological therapy, CRT May Be Appropriate depending on the presence or absence of LBBB and/or a QRS duration ≥150 ms (Table 7.6). In short, no single parameter is the sole determinant for choosing CRT or predicting response to it.

FIGURE 18 Summary of Table 7.3, CRT: LVEF >35% to 50% of Any Etiology (ICD Indicated)



AF = atrial fibrillation; amb = ambulatory; CRT = cardiac resynchronization therapy; ICD = implantable cardioverter-defibrillator; LBBB = left bundle branch block; LVEF = left ventricular ejection fraction; M = May Be Appropriate; NYHA = New York Heart Association; R = Rarely Appropriate; SR = sinus rhythm.

TABLE 7.7 Heart Failure With RV dysfunction

Indication		Appropriate Use Score (1-9)
Heart Failure		
270.	■ Inferior MI ■ LVEF >35% ■ Severe RV dysfunction ■ No indication for ventricular pacing ■ QRS 120-149 ms ■ Non-LBBB ■ NYHA functional class III-amb IV	3 (R)

amb = ambulatory; LBBB = left bundle branch block; LVEF = left ventricular ejection fraction; MI = myocardial infarction; NYHA = New York Heart Association; R = Rarely Appropriate; RV = right ventricular.

The combination of NYHA functional class, QRS duration, QRS morphology (LBBB vs non-LBBB), the degree of LV dysfunction (LVEF), and the presence of sinus rhythm (vs AF) all influence the strength of the recommendation for or against CRT.

Consistent with accumulating data indicating the potential detrimental effects of RV pacing,[145] when there is pre-existing or anticipated RV pacing with a clinical indication for ICD or PM implantation, CRT is deemed Appropriate as the percentage of anticipated RV pacing increases (Table 7.5).

The concept of CRT is evolving to encompass traditional LV epicardial pacing using a lead deployed via a coronary sinus (CS) branch to a LV vein, as well as HBP and LBB area pacing, eg, conduction system pacing (CSP).[2] Further study is needed to determine what are the best measures of CRT/CSP response and how they compare. Technologies to ease implantation are always evolving, as are those for resynchronization.[146]

Section 8: Heart Failure: LVAD

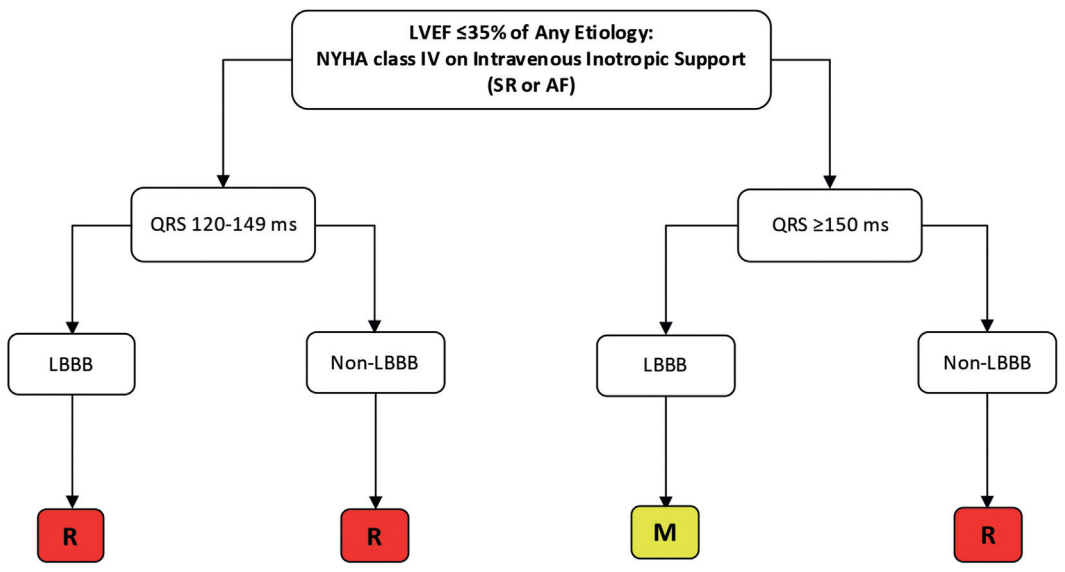
Assumptions and Considerations

Because patients on LVAD support are less dependent of LV filling for maintaining adequate cardiac output than patients not on mechanical circulatory support, they tolerate sustained VT and VF better than patients without LVAD support; however, cardiac output is decreased during sustained ventricular arrhythmias, and patients are frequently symptomatic. The data on the need for ICD in such patients are conflicting.

Whereas the majority of studies, mostly observational, and meta-analyses showed no survival benefit in LVAD patients with ICDs,[147-150] some demonstrated a survival advantage with ICDs.[151,152] Therefore, patients who did not have ICDs implanted prior to LVAD may be considered for ICD implantation after LVAD, and patients with pre-existing ICDs should have them turned on after the LVAD.

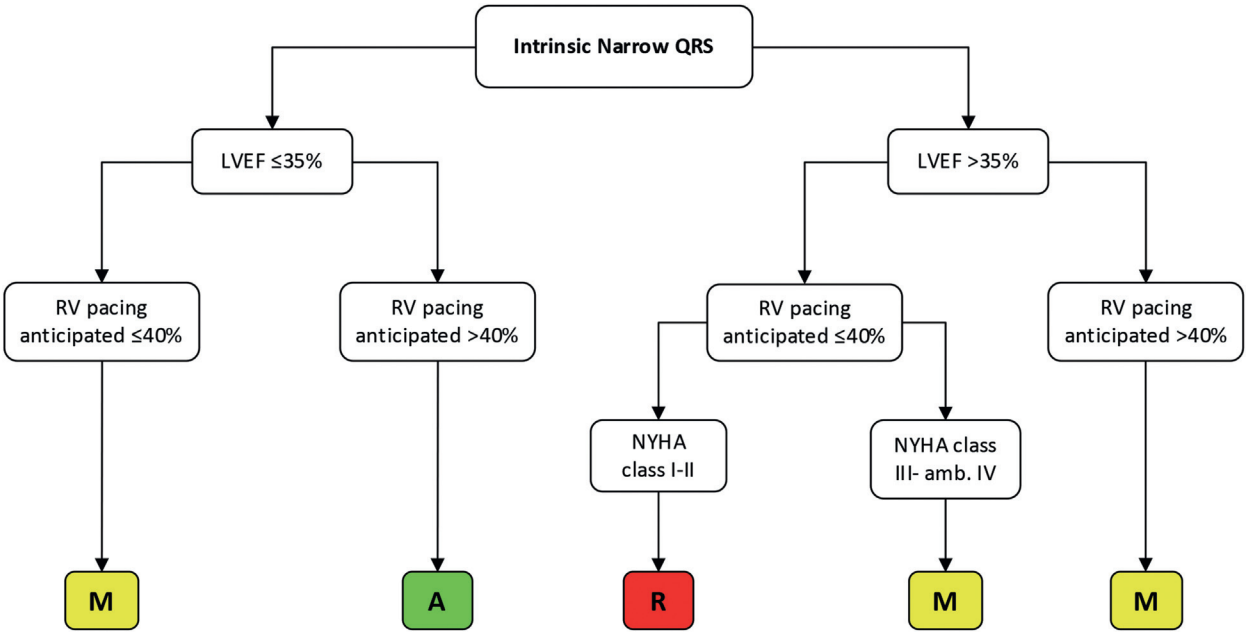
When an ICD is in place, routine care, including regular interrogations and generator replacement is usually maintained. When more extensive interventions such as lead replacement/repositioning are needed, careful consideration should be given to the risk/benefit ratio, because LVAD patients are typically on chronic anticoagulation and may have higher complication rates after invasive procedures than the general ICD population.

FIGURE 19 Summary of Table 7.4, CRT: LVEF ≤35% of Any Etiology



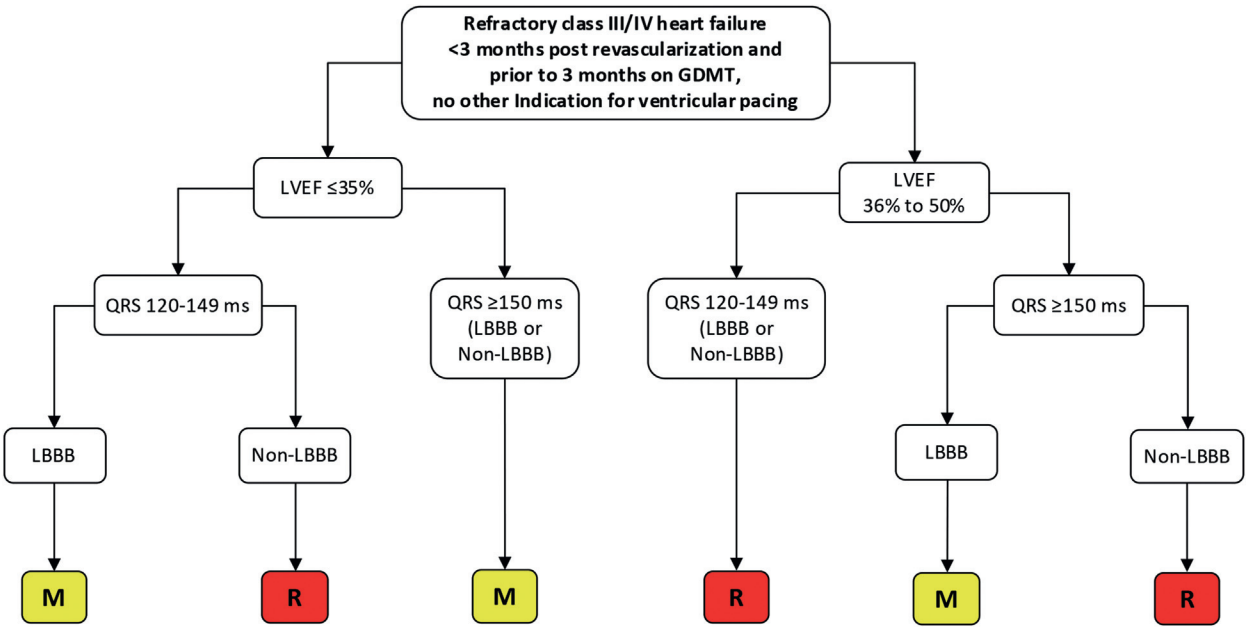
AF = atrial fibrillation; CRT = cardiac resynchronization therapy; LBBB = left bundle branch block; LVEF = left ventricular ejection fraction; M = May Be Appropriate; NYHA = New York Heart Association; R = Rarely Appropriate; SR = sinus rhythm.

FIGURE 20 Summary of Table 7.5, CRT Pre-Existing or Anticipated RV Pacing With a Clinical Indication for ICD or Pacemaker Implantation



A = Appropriate; amb = ambulatory; CRT = cardiac resynchronization therapy; ICD = implantable cardioverter-defibrillator; LVEF = left ventricular ejection fraction; M = May Be Appropriate; NYHA = New York Heart Association; R = Rarely Appropriate; RV = right ventricular.

FIGURE 21 Summary of Table 7.6, Refractory Class III/IV HF <3 Months Postrevascularization



GDMT = guideline-directed medical therapy; LBBB = left bundle branch block; LVEF = left ventricular ejection fraction; M = May Be Appropriate; R = Rarely Appropriate.

TABLE 8.1 Cardiomyopathy and LVAD With Pre-Existing ICD

Indication	Appropriate Use Score (1-9)
271. ■ Keeping ICD on while patient is on LVAD support	M (6)
272. ■ Generator change in battery end of life ■ *Primary* prevention ICD and patient has *not* received any appropriate ICD therapies from prior ICD	M (4)
273. ■ Generator change in battery end of life ■ *Secondary* prevention ICD or patient *has* received appropriate ICD therapy from prior ICD	M (6)
274. ■ Maximizing ATP therapies and prolonging detection time in patient on LVAD support with appropriate ICD shocks	A (7)
275. ■ Deactivation of tachyarrhythmia therapies in a patient on LVAD support with inappropriate ICD shocks for atrial tachycardia or atrial fibrillation	M (6)
276. ■ Deactivation of tachyarrhythmia therapies in a patient on LVAD support with appropriate shocks for VT/VF on patient's request	A (8)
277. ■ Deactivation of tachyarrhythmia therapies in patients with biventricular assist devices who are in persistent VT/VF or who have frequent sustained runs of VT despite optimal anti-arrhythmic therapy	A (7)

A = Appropriate; ATP = antitachycardia pacing; ICD = implantable cardioverter-defibrillator; LVAD = left ventricular assist device; M = May Be Appropriate; VF = ventricular fibrillation; VT = ventricular tachycardia.

Given relatively good tolerability of VT/VF post-LVAD, many cardiologists program ICDs to minimize shocks and maximize antitachycardia pacing. Specifically, recommendations have been made to set the VF zone with high-rate cutoff (240-250 beats/min) with the longest programmable detection time available on the device. For the VT zone, multiple runs of ATP should be programmed because they can prevent or significantly delay ICD shock delivery.[153,154]

S-ICDs can also be considered in patients with LVADs because of potentially less risk of infection,[155] although reported interference with LVADs may create difficulties for ICD interrogation, and no ATP will be available with currently approved technology.[154]

ICD inactivation may be considered at a patient's request if frequent shocks cannot be controlled by reprogramming or antiarrhythmic therapies.[153]

Benefits of CRT in LVADs are even more controversial than ICD therapy. Patients who respond favorably to CRT usually do not require an LVAD, and those who are so hemodynamically compromised that an LVAD is indicated clearly are nonresponders. To date, there is no evidence of any survival or symptomatic benefits of CRT in patients on LVAD support.[156-161] In 1 small randomized study, RV pacing compared with biventricular (BiV) pacing was associated with a significantly improved functional status, QOL, and fewer ventricular tachyarrhythmias in LVAD patients with prior CRT.[160] Therefore, turning off the LV lead may provide longer battery life without compromise to morbidity or survival.[158]

Tables 8.1 to 8.4 and Figures 22 and 23 describe HF scenarios in patients with LVADs with and without pre-existing ICDs or CRT.

TABLE 8.2 Cardiomyopathy and LVAD Without Pre-Existing ICD

Indication	Appropriate Use Score (1-9)
278. ■ De novo *transvenous* ICD implant in a patient on LVAD support for primary prevention of sudden cardiac death	M (4)
279. ■ De novo *subcutaneous* ICD implant in a patient on LVAD support for primary prevention of sudden cardiac death	M (4)
280. ■ De novo *transvenous* ICD implant in a patient on LVAD support with history of cardiac arrest or history of sustained VT	M (6)
281. ■ De novo *subcutaneous* ICD implant in a patient on LVAD support with history of cardiac arrest or history of sustained VT	M (4)

ICD = implantable cardioverter-defibrillator; LVAD = left ventricular assist device; M = May Be Appropriate; VT = ventricular tachycardia.

TABLE 8.3 Cardiomyopathy and LVAD With Pre-Existing CRT-D

Indication	Appropriate Use Score (1-9)
282. ■ Keep the CRT settings unchanged in a patient on LVAD support	M (5)
283. ■ Discontinue LV pacing in patient on LVAD support due to futility and for increasing battery life	M (6)

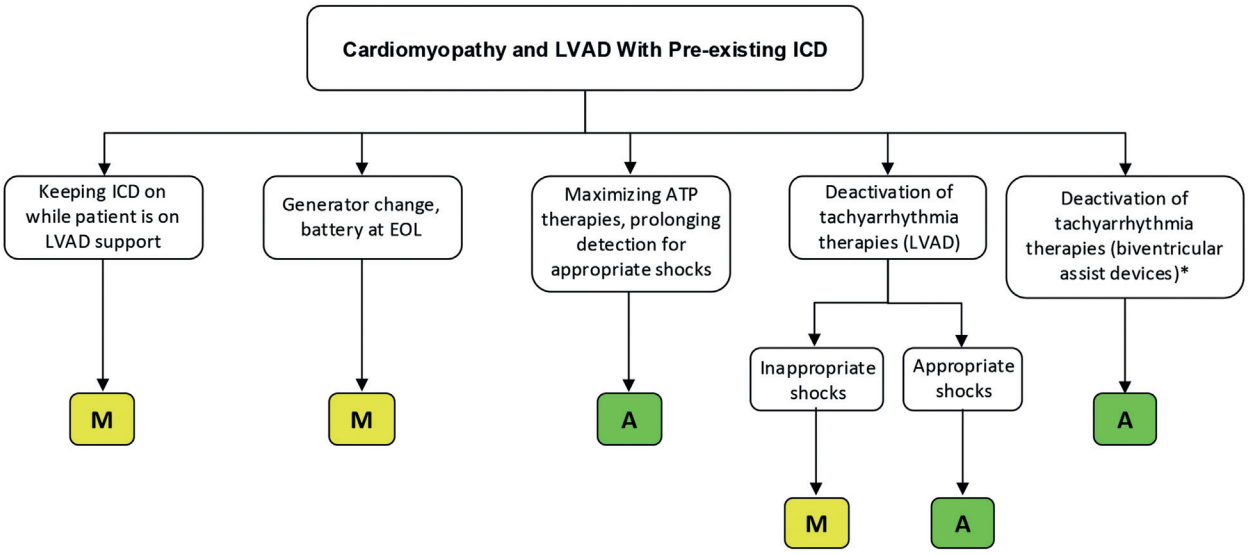
CRT = cardiac resynchronization therapy; CRT-D = cardiac resynchronization therapy with defibrillator; LV = left ventricular; LVAD = left ventricular assist device; M = May Be Appropriate.

TABLE 8.4 Cardiomyopathy and LVAD Without Pre-Existing CRT-D

Indication	Appropriate Use Score (1-9)	
	QRS 120-149 ms	QRS ≥150 ms
284. ■ Implantation of CRT-D or upgrading existing ICD to CRT-D in patient on LVAD support and *non-LBBB* morphology	R (2)	R (3)
285. ■ Implantation of CRT-D or upgrading existing ICD to CRT-D in patient on LVAD support and *LBBB* morphology	R (2)	R (3)

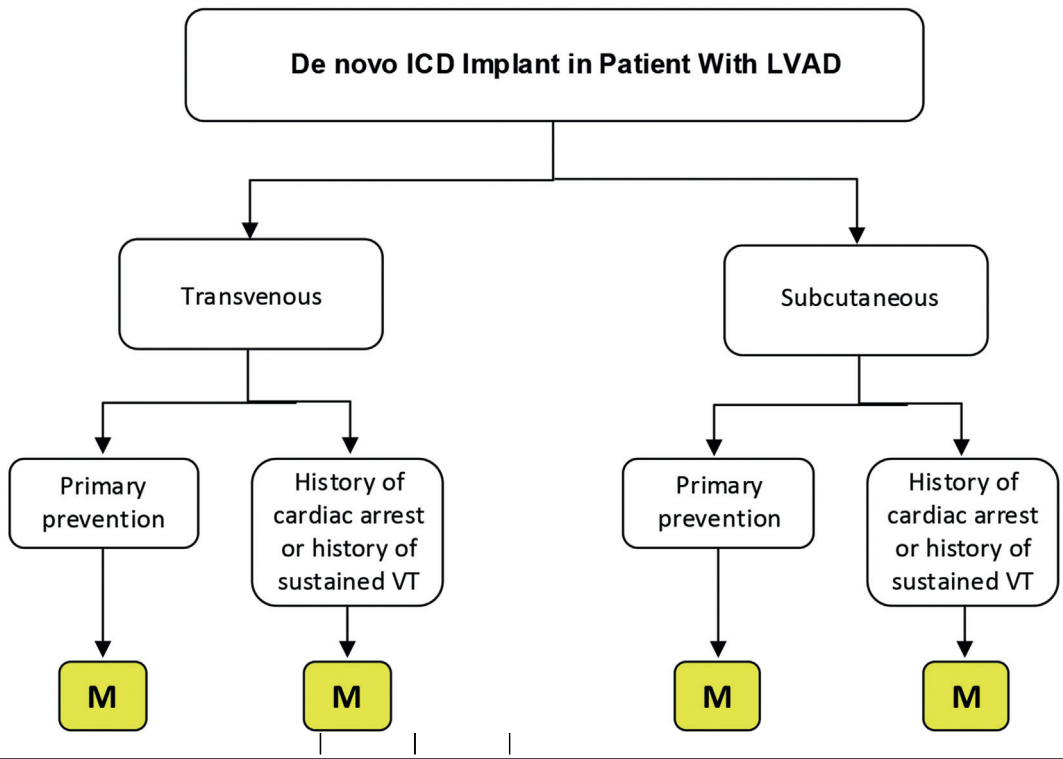
CRT-D = cardiac resynchronization therapy with defibrillator; ICD = implantable cardioverter-defibrillator; LBBB = left bundle branch block; LVAD = left ventricular assist device; R = Rarely Appropriate.

FIGURE 22 Summary of Table 8.1, Cardiomyopathy and LVAD With Pre-Existing ICD



*Who are in persistent VT/VF or who have frequent sustained runs of VT despite optimal antiarrhythmic therapy A = Appropriate; ATP = antitachycardia pacing; EOL = end of life; ICD = implantable cardioverter-defibrillator; LVAD = left ventricular assist device; M = May Be Appropriate.

FIGURE 23 Summary of Table 8.2, Cardiomyopathy and LVAD Without Pre-Existing ICD



ICD = implantable cardioverter-defibrillator; LVAD = left ventricular assist device; M = May Be Appropriate; VT = ventricular tachycardia.

Section 8 Results and Discussion

In patients receiving LVAD support, ICD and CRT therapy is not well defined by large clinical trials. This lack of data is reflected by the large number of ICD indications that were rated May Be Appropriate, which includes continuing ICD therapy and generator change. Attempts to minimize ICD shocks were rated Appropriate. De novo ICD implant was considered May Be Appropriate for primary prevention or secondary prevention, likely due to the tolerability to VT/VF in many patients on LVAD support.

In patients supported by LVAD, keeping CRT therapy on for putative LV remodeling benefit or turning it off to increase battery life were both rated the same, May Be Appropriate. Implanting a de novo CRT with defibrillator (CRT-D) or upgrading an ICD to a CRT-D was rated Rarely Appropriate whether LBBB or non-LBBB morphology was present. A recent review of LVAD and CIED has been published.[162]

Section 9: HF: ICD Implantation After Heart Transplantation (Without Documented Sustained Ventricular Arrhythmias Posttransplant)

Assumptions and Considerations

Heart Transplant

A significant proportion of heart transplant recipients die suddenly, with SCD being responsible for 10% to 35% of deaths in this population.[163,164] The risk of SCD after cardiac transplantation is currently about 1.30 per 100 person-years, which is 4-fold higher than in general population.[165] Moreover, this risk is increasing with time. Independent predictors of increased risk of SCD are older donor age, younger recipient age, non-White race, post-transplant graft dysfunction (LVEF <40%), nonskin cancer, infection, rejection, and posttransplant vasculopathy.[163,165]

History of treated rejection during the first post-transplant year was associated with a 1.76-fold increased risk of SCD (HR: 1.76; 95% CI: 1.35-2.30) whereas cardiac allograft vasculopathy (CAV) was associated with 3.32-fold increased risk of SCD (HR: 3.32; 95% CI: 2.73-4.03).[165] A combination of these 2 factors further increases risk.

Not all SCD after heart transplant is arrhythmic in nature, and not all arrhythmic SCD is preventable by ICD therapy. Patients die suddenly even with normally functioning ICDs due to electromechanical dissociation after successful defibrillation.[166] Moreover, in a retrospective analysis of modes of death in 26 transplant recipients with terminal rhythm available for analysis, asystole was the most common rhythm (34%), followed by pulseless electrical activity (20%) and VF (10%).[164] Other studies described bradyarrhythmias, asystole, and electromechanical dissociation as leading abnormalities of SCD.[167,168]

Nevertheless, when ICDs were implanted in patients post-cardiac transplant with a history of rejection and CAV, 25% of patients received appropriate ICD shocks for VT or VF, resulting in a successful treatment of a potentially impending SCD.[167,168] In other series, when severe allograft vasculopathy, unexplained syncope, history of cardiac arrest, and severe LV dysfunction were considered an indication for ICD implantation, 22 shocks were delivered to 28% of patients, of whom 80% received appropriate shocks for either rapid VT or VF.[168] Interestingly, all patients with appropriate shocks had severe CAV, and none had rejection. CAV may result in myocardial ischemia, scarring, and create a substrate for arrhythmia.[167] This condition is also associated with a prolonged QT interval.[169]

In 2009, a U.S. national survey of ICDs in transplant recipients identified 44 patients who had received defibrillators. The appropriate shock rate was 13.6% with an inappropriate shock rate of 6.8%.[170]

Table 9.1 and **Figure 24** describe HF situations where ICD implantation after heart transplantation might be considered in the absence of sustained ventricular arrhythmias.

Section 9 Results and Discussion

While the necessity to consider ICD placement for a heart transplantation recipient is infrequent in daily clinical practice, the risk of SCD, including arrhythmic death, is real in this population. In fact, this risk can surpass similar risks in the general population by 20 times or more. In a cohort of heart transplant recipients beyond first year after the transplant, the annual incidence of SCD was 12.5 per 1,000 person-years, compared with that of 0.54 per 1,000 person-years in the general population ($P < 0.001$), especially in the youngest recipients.[171] Apart from demographic factors, decreased LVEF was identified as a risk factor for SCD, as reflected in our appropriateness criteria (**Table 9.1**, **Figure 24**).

At the same time, the risks of ICD implantation are higher in heart transplant recipients than in the general population, primarily due to chronic lifelong immunosuppression, which increases the risk for infection. For this reason, even with the history of rejection and CAV, the ICD was deemed May Be Appropriate. This level of appropriateness also considers a higher complexity of implantation procedure, considering that many patients had implantable devices before the transplant, and sometimes retained fragments of the pacing wires, leading to access difficulties.

TABLE 9.1 ICD Implantation in Heart Transplant Recipients, No Sustained Ventricular Arrhythmias

Indication	Appropriate Use Score (1-9) LVEF 36%-50%	LVEF ≤35%
286. ■ Heart transplant recipient ■ History of multiple episodes of cellular or antibody-mediated rejection	M (5)	A (7)
287. ■ Heart transplant recipient ■ Evidence of cardiac allograph vasculopathy	M (6)	
288. ■ Heart transplant recipient ■ LVEF ≤35% of any etiology		M (6)

NOTE: gray shaded box indicates "not rated."

A = Appropriate; ICD = implantable cardioverter-defibrillator; LVEF = left ventricular ejection fraction; M = May Be Appropriate.

Section 10: HF and CCM

It should be noted that despite FDA approval of this device, postapproval clinical experience still remains very limited at most centers.

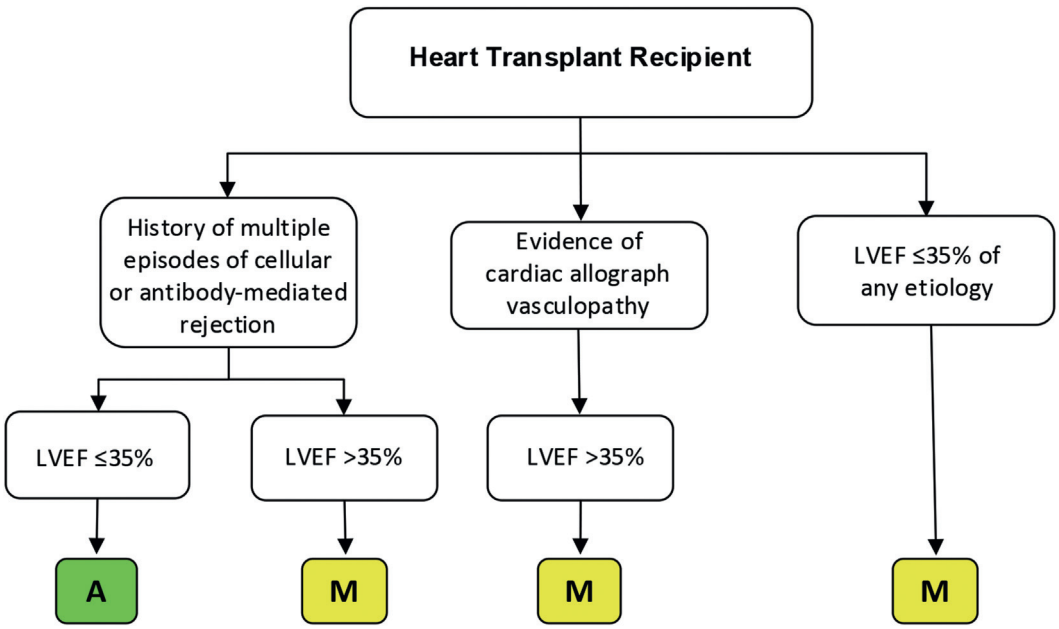
Assumptions and Considerations

- Optimal medical therapy (GDMT) for HF.
- Consider separate from ICD indication.
- Assume it is feasible to implant additional hardware if ICD is in place.
- Assume QRS duration <130 ms.

Although CRT has been shown to be an effective treatment for patients with systolic HF, prolonged QRS duration (≥120 ms), and HF symptoms despite GDMT, many patients with HF have a QRS duration <120 ms and do not meet criteria for CRT. CCM has emerged as a promising treatment for patients with chronic HF with reduced EF who are not indicated for CRT. CCM is an electrical therapy where nonexcitatory, high-voltage, biphasic electrical pulses are delivered to the RV septum during the absolute refractory period of myocardial cells.[55,172-175] Despite the high voltage, these pulses do not initiate contraction, as they are delivered 30 to 40 ms after local myocardial activation during the absolute refractory period.[172] Although the precise molecular mechanisms underlying the effects of CCM are not completely understood, studies suggest that CCM may enhance the strength of myocardial contraction through changes in cardiomyocyte calcium flux or modification and expression of genes coding for proteins involved in calcium regulation.[175,176]

Several randomized studies were performed evaluating the efficacy and safety of CCM in patients with EF ranging

FIGURE 24 Summary of Table 9.1, ICD Implantation in Heart Transplant Recipients, No Sustained Ventricular Arrhythmias



A = Appropriate; ICD = implantable cardioverter-defibrillator; LVEF = left ventricular ejection fraction; M = May Be Appropriate.

TABLE 10.1 Heart Failure and CCM

Indication	Appropriate Use Score (1-9)	
NYHA Functional Class	II	III-IV
CCM, Not Candidate for CRT (QRS <130 ms)		
289. ■ LVEF <25%	M (4)	M (4)
290. ■ LVEF 25%-≤35%	M (4)	M (5)
291. ■ LVEF 36%-≤45%	M (4)	M (4)

CCM = cardiac contractility modulation; CRT = cardiac resynchronization therapy; LVEF = left ventricular ejection fraction; M = May Be Appropriate; NYHA = New York Heart Association.

from 25% to 45%.[172,177-180] CCM has been studied in patients with symptomatic HF on GDMT with LVEF <45% who are not eligible for CRT and has been shown to be safe and effective, improving QOL, NYHA functional classification, 6MWT distance, and peak VO_2 (maximum oxygen uptake).[172,177,179,181] While studies have not been powered for morbidity or mortality, in patients with NYHA functional class III or IV symptoms, QRS duration <130 ms, and LVEF >25% and <45%, 1 study showed that the composite outcome of cardiovascular death and HF hospitalizations was reduced from 10.8% to 2.9% ($P = 0.048$).[177] A meta-analysis of 861 subjects in a pooled analysis showed that CCM significantly improved peak VO_2, 6MWT distance, and QOL measured by Minnesota Living With Heart Failure Questionnaire compared with that of the control group.[182]

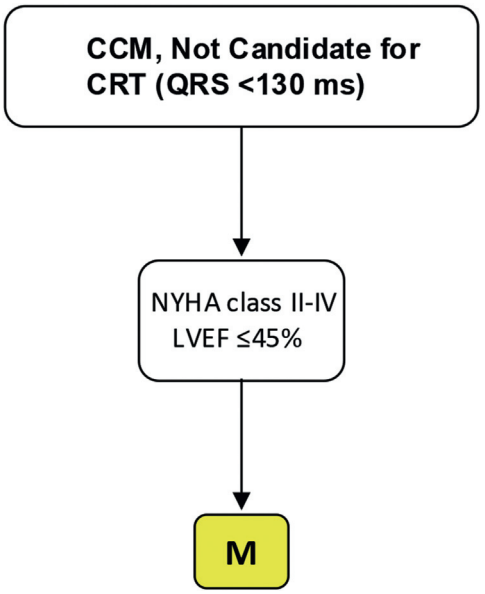
The FDA approved CCM (Impulse Dynamics Optimizer® Smart System) with a Breakthrough Device designation in 2019 to improve 6MWT distance and QOL in patients with NYHA functional class III HF who remain symptomatic despite GDMT, with LVEF ranging from 25% to 45%, who are in sinus rhythm and not indicated for CRT.[183] Although the "2022 AHA/ACC/HFSA Guideline for the Management of Heart Failure" acknowledges that CCM has been associated with augmentation of LV contractile performance, specific recommendations were not yet included in this guideline.[33] Similarly, the "2021 ESC Guidelines for the Diagnosis and Treatment of Acute and Chronic Heart Failure" acknowledge a small improvement in exercise tolerance and QOL with CCM in patients with NYHA functional class III to IV HF, with an LVEF >25% to <45%, and QRS duration <130 ms, but no specific guideline recommendations were listed.[184] The full effect of CCM on HF morbidity and mortality requires further investigation.

Table 10.1 and Figure 25 describe HF situations where CCM might be considered.

Section 10 Results and Discussion

While CCM studies were primarily performed in patients with NYHA functional class III to IV HF who were not indicated for CRT with LVEF ranging between 25% to 45%, and the FDA approved the device only for NYHA functional class III HF patients, recommendations of May Be Appropriate were given for NYHA functional classes II and III to IV categories by the rating panel (Table 10.1, Figure 25). In addition, there are currently no practice guideline recommendations for CCM. The lack of differentiation of AUC recommendations according to HF class as well as the paucity of U.S. or European guideline recommendations likely reflect the strength of evidence related to hard clinical outcomes, such as HF hospitalization and mortality. Studies evaluating longer-term clinical outcomes and impact of CCM on reverse remodeling in larger cohorts are needed.

FIGURE 25 Summary of Table 10.1, Heart Failure and CCM



CCM = cardiac contractility modulation; CRT = cardiac resynchronization therapy; LVEF = left ventricular ejection fraction; M = May Be Appropriate; NYHA = New York Heart Association.

Section 11: Leadless Pacing, Bradycardia Pacing

Assumptions and Considerations

- It is assumed there is currently no indication for ICD therapy unless otherwise specified.
- For patients with LVEF ≤35% on GDMT for ≥3 months, patients would also be a candidate for an ICD (unless older or frail patient, etc). If an ICD is also needed, an S-ICD could be considered with appropriate testing and programming to avoid device-device interactions.
- If the patient is not an ICD candidate, then patients have indications for a permanent PM.

TABLE 11.1 Patient, Device Longevity, and Rhythm Considerations

Indication		Appropriate Use Score (1-9)	
Long-Standing Persistent or Permanent AF and Normal LVEF		**Anticipated Pacing ≥40%**	**Anticipated Pacing <40%**
292.	■ Leadless device longevity anticipated to be longer than patient survival	**M (6)**	**A (7)**
293.	■ Patient survival anticipated to be longer than leadless device longevity	**M (4)**	**M (6)**
Persistent or Permanent AF and LVEF 36%-50%		**Anticipated Pacing ≥40%**	**Anticipated Pacing <40%**
294.	■ Leadless device longevity anticipated to be longer than patient survival	**M (4)**	**M (5)**
295.	■ Patient survival anticipated to be longer than leadless device longevity	**M (4)**	**M (4)**
		Anticipated Pacing ≥40%	
Sinus Rhythm With Complete Heart Block and Normal LVEF			
296.	■ Leadless device longevity anticipated to be longer than patient survival	**M (5)**	
297.	■ Patient survival anticipated to be longer than leadless device longevity	**M (5)**	
Sinus Rhythm With Complete Heart Block and LVEF 36%-50%			
298.	■ Leadless device longevity anticipated to be longer than patient survival	**M (4)**	
299.	■ Patient survival anticipated to be longer than leadless device longevity	**R (3)**	

A = Appropriate; AF = atrial fibrillation; LVEF = left ventricular ejection fraction; M = May Be Appropriate; R = Rarely Appropriate.

- VDD pacing capability is available for single-chamber (RV) leadless devices and now modular AV dual-chamber pacing devices are also available that can pace in DDD mode.[185]
- Device longevity may require considerations of future replacements or additional devices in younger patients.

Permanent pacing is indicated for symptomatic bradycardia that is not from reversible causes. Permanent pacing improves QOL in patients with sinus node dysfunction, AV block, and AF with slow AV conduction. Permanent pacing also reduces mortality in patients with asystole and AV block.[6,186] Approximately 1 million transvenous PMs are implanted worldwide every year.[187] However, transvenous PMs are associated with a significant (9%-12%) complication rate, including pocket hematomas, pocket infections, lead failure, endocarditis, and pulse generator malfunction.[188] Transvenous leads are among the most vulnerable components of pacing systems. Lead-related complications include lead fracture, insulation failure (1%-4%), and lead dislodgement (~1.6% incidence).[189] In addition, transvenous leads may also cause venous obstruction and tricuspid regurgitation with their own negative ramifications.[190] Transvenous leads may require extraction due to device infection or other indications. Extraction of transvenous leads carry risks of vascular and cardiac laceration; while these risks are infrequent (1% to 2%), they can lead to thoracotomy or death. Finally, some patients cannot benefit from transvenous leads because of extensive venous occlusion, as can occasionally be encountered in patients with end-stage renal failure on dialysis.

Given the limitations and risks associated with transvenous pacing leads, the leadless PM was developed to overcome many of these issues. Clinical trial data demonstrated significantly fewer complications with leadless pacing relative to transvenous single-chamber PMs with similar efficacy (sensing and pacing thresholds).[191] Leadless pacing also appears to be associated with lower rates of device infection[192]; however, leadless PMs are not without risk, including risk of device dislodgment and RV perforation/tamponade (<1%).[193]

There are drawbacks of currently available leadless pacing devices. The original devices approved at the time of the AUC panel ratings only provided ventricular pacing, and therefore, risk for PM syndrome should be considered. Leadless pacing is an attractive option in patients with AF and slow ventricular response who do not require ICD or CRT therapy. Patients with intact sinus function may be appropriate candidates for single-chamber ventricular leadless pacing if they have infrequent requirements for pacing, such as rare but significant sinus pauses.[194] One device is able to provide VDD pacing in patients with intact sinus function and AV block via accelerometer-based sensing of atrial activity.[195] More recently, modular devices (1 device placed in the atrium

TABLE 11.2 Venous Access Issues

Indication		Appropriate Use Score (1-9)	
		Anticipated Pacing ≥40%	**Anticipated Pacing <40%**
No Upper Extremity Access and Symptomatic Bradycardia			
300.	■ LVEF ≤35% (ICD indication, S-ICD, or epicardial)	**M (4)**	**M (5)**
301.	■ LVEF 36%-50%	**M (5)**	**M (6)**
302.	■ LVEF >50%	**A (7)**	**A (7)**

A = Appropriate; ICD = implantable cardioverter-defibrillator; LVEF = left ventricular ejection fraction; M = May Be Appropriate; S-ICD = subcutaneous implantable cardioverter-defibrillator.

TABLE 11.3 Prior CIED Infection

Indication	Appropriate Use Score (1-9)	
	Anticipated Pacing ≥40%	Anticipated Pacing <40%
Multiple CIED Infections and Symptomatic Bradycardia		
303. ■ LVEF ≤35% (ICD indication, S-ICD, or epicardial)	M (5)	M (6)
304. ■ LVEF 36%-50%	M (5)	M (6)
305. ■ LVEF >50%	M (6)	A (7)

A = Appropriate; CIED = cardiovascular implantable electronic device; ICD = implantable cardioverter-defibrillator; LVEF = left ventricular ejection fraction; M = May Be Appropriate; S-ICD = subcutaneous implantable cardioverter-defibrillator.

and 1 device placed in the ventricle) can provide DDD pacing. While leadless PMs have been hypothesized to minimize tricuspid regurgitation, some data suggest that tricuspid function may still be impacted by leadless pacing.[196] Finally, it is important to recognize that patients who have difficulties with traditional transvenous pacing have options other than leadless PMs, including epicardial pacing and femoral transvenous systems.

Tables 11.1 to 11.6 and Figures 26 to 27 describe scenarios where leadless pacing may be considered, modified by anticipated pacing frequency, concomitant atrial arrhythmias, LVEF, venous access issues, prior CIED infection, or other clinical scenarios. With rapid advancements in leadless device technology, the writing group acknowledges that indications may change with time, particularly with more recent availability of dual-chamber leadless pacing and anticipated future availability of conduction system pacing with leadless devices.

Section 11 Results and Discussion

As with many technologies, patient selection is one of the most important steps to ensure optimal effectiveness and safety of permanent pacing. Leadless pacing offers the benefits of pacing without the risks associated with PM pockets and transvenous leads; however, there are 2 primary limitations of current leadless PMs. First and foremost, at the present time, current leadless PMs only provide RV pacing and thus carry risks of pacing-induced

TABLE 11.4 AV Junction Ablation in a Patient With Long-Standing Persistent or Permanent AF

Indication	Appropriate Use Score (1-9)
306. ■ LVEF ≤35% (ICD indication*)	R (3)
307. ■ LVEF 36%-50%	M (5)
308. ■ LVEF >50%	A (7)

*If S-ICD is chosen, testing must be done to avoid and ensure the absence of device-device interaction.

A = Appropriate; AF = atrial fibrillation; AV = atrioventricular; ICD = implantable cardioverter-defibrillator; LVEF = left ventricular ejection fraction; M = May Be Appropriate; R = Rarely Appropriate.

TABLE 11.5 Other Clinical Scenarios

Indication	Appropriate Use Score (1-9)
309. ■ Indication for ventricular pacing and prior tricuspid valve surgery (eg, repair or bio-prosthetic valve)	M (6)
310. ■ Intermittent sinus node arrest	M (5)
311. ■ Neurocardiogenic syncope with a profound cardio-inhibitory response	M (6)
312. ■ Tachy-brady with symptomatic postconversion pauses	M (4)
313. ■ Pacing as a bridge in infected patients undergoing extraction (ie, temporary use)	M (6)

M = May Be Appropriate.

CM. Due to the risk of RV pacing-induced CM, appropriate use of these devices is optimal when there is no evidence of LV dysfunction and the burden of pacing is expected to be low; however, there are instances when the benefits of leadless pacing could outweigh the increased risk for RV pacing-induced CM. Some situations may include patients who have limited vascular options for transvenous pacing and those with prior device infection, since leadless PMs are associated with a much lower infection risk.[197]

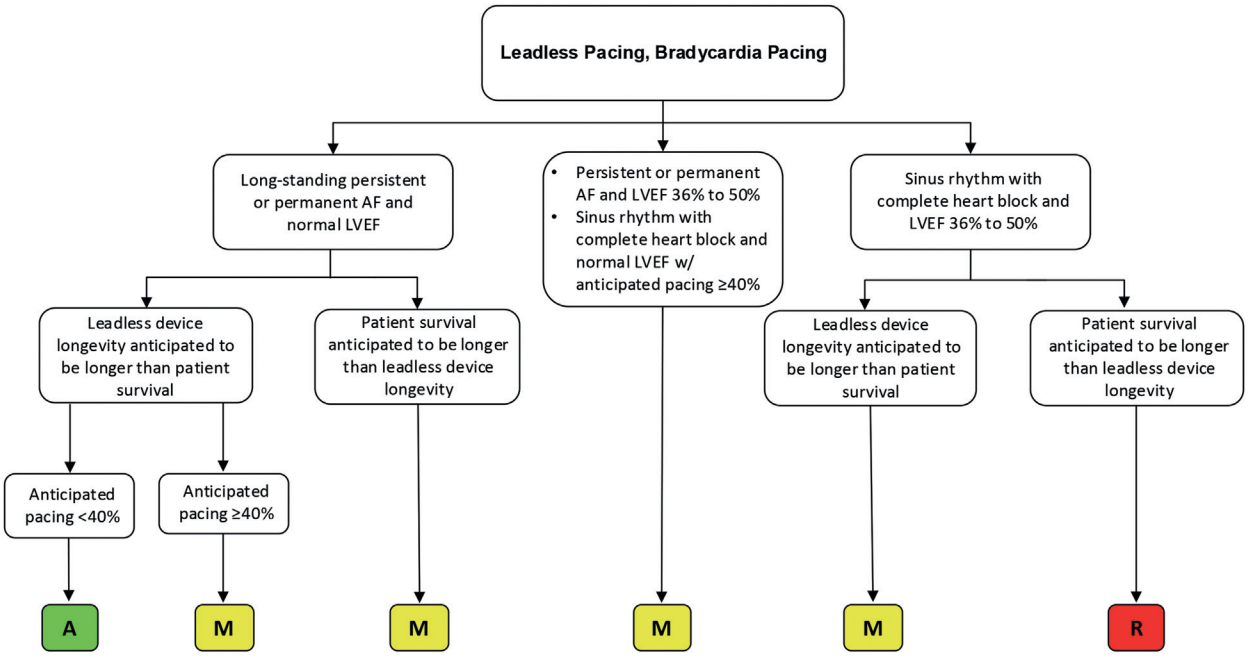
A second major limitation of leadless pacing devices is the complicated nature of device replacement, particularly in young patients who could require ≥3 devices in long-term follow-up. There are several concerns with leadless PM device replacement, including adequate space to accommodate additional devices and the potential for mechanical device-device interactions. While extraction of leadless PMs is feasible in some cases, it is associated with risks, particularly in devices that are significantly encapsulated by fibrosis. Thus, leadless pacing is most optimal when patients will only require 1 device to meet their lifelong pacing needs. This is reflected in the AUC. For example, in persons with long-

TABLE 11.6 Subcutaneous ICD, Previously Implanted, Need for Pacing (Leadless Pacing)

Indication	Appropriate Use Score (1-9)
Patient With AF, Symptomatic Bradycardia, and Anticipated Pacing <40% With Pre-Existing Subcutaneous ICD	
314. ■ LVEF ≤35% ■ Persistent or permanent AF	M (5)
315. ■ LVEF 36%-50% ■ Persistent or permanent AF	M (6)
316. ■ LVEF >50% ■ Persistent or permanent AF	A (7)
317. ■ Patient with paroxysmal AF, bradycardia (infrequent pacing anticipated), and a subcutaneous ICD	A (7)

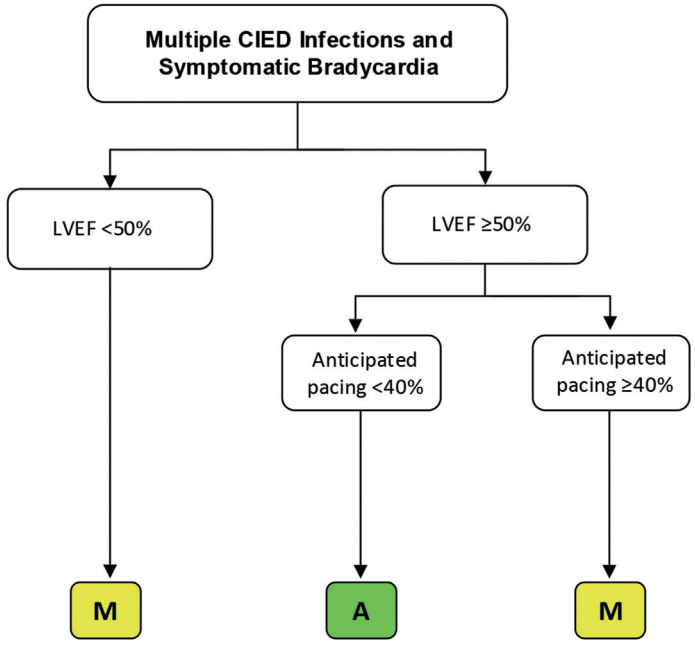
A = Appropriate; AF = atrial fibrillation; ICD = implantable cardioverter-defibrillator; LVEF = left ventricular ejection fraction; M = May Be Appropriate.

FIGURE 26 **Summary of Table 11.1, Leadless Pacing, Bradycardia Pacing: Patient, Device Longevity, and Rhythm Considerations**



*It is assumed that: 1) there is currently no indication for ICD therapy; and 2) considerations include the need for possible generator replacements. A = Appropriate; AF = atrial fibrillation; ICD = implantable cardioverter-defibrillator; LVEF = left ventricular ejection fraction; M = May Be Appropriate; R = Rarely Appropriate.

FIGURE 27 **Summary of Table 11.3, Leadless Pacing, Bradycardia Pacing: Prior CIED Infection**



A = Appropriate; CIED = cardiovascular implantable electronic device; LVEF = left ventricular ejection fraction; M = May Be Appropriate.

standing persistent or permanent AF, the anticipated need for pacing is <40% and the patient longevity is estimated to be shorter than the battery longevity, leadless pacing is Appropriate. In other situations (eg, sinus rhythm with complete heart block) and when patient longevity is greater than the anticipated device longevity, leadless pacing May Be Appropriate with normal LV function but is Rarely Appropriate with LV dysfunction.

There are occasions where traditional transvenous pacing is not possible. In persons with no upper extremity access and symptomatic bradycardia and an LVEF of ≥50%, leadless pacing is Appropriate. In persons with no upper extremity access and LVEF <50%, it May Be Appropriate. In the case of AV node ablation for long-standing persistent or permanent AF, leadless pacing is Appropriate when the LVEF is ≥50%, May Be Appropriate when there is moderate LV dysfunction, and is Rarely Appropriate when LVEF is ≤35%. It is important to note that in persons with LV dysfunction, placement of a physiological pacing system may be a much better option.

A more controversial topic is the use of leadless PMs in persons with S-ICDs. The use of these devices in the same patient offers the promise of reduced risk of endovascular infection with the capability of pacing. Despite these potential advantages, there are risks of adverse device-device interactions. Leadless PMs do not utilize unipolar pacing and thus are not absolutely contraindicated in persons with S-ICDs; however, potential interactions include challenges with sensing, including increased risks of T-wave oversensing with intermittent pacing due to changes in the QRS complexes and R:T ratio. Thus, when using leadless pacing and an S-ICD, careful attention must be given to appropriate S-ICD sensing to avoid oversensing and undersensing of VF. Despite these concerns, the rating panel indicated that use of leadless PMs in those with LVEF of ≥50% and an anticipated pacing burden <40% is Appropriate and May Be Appropriate in those with worse LV function. Published case series have demonstrated proof of concept in small numbers of patients.[198] The combination of these devices may be particularly helpful in persons with complex anatomy and limited vascular options. Prospective trials of devices from the same manufacturer with intercommunication are testing the safety and efficacy of these devices and their ability to provide modular antitachycardia pacing for treatment of VT.[199,200] Initial results of the MODULAR ATP trial were recently published demonstrating effective wireless communication between the leadless PM and S-ICD exceeding prespecified performance goals for safety and efficacy during implant and 6-month follow-up.[200]

Whereas persons with long-standing persistent or permanent AF only require ventricular pacing, patients in sinus rhythm benefit from AV synchrony, especially when there is expected to be a high frequency of RV pacing, as in the case of complete heart block. Some RV leadless PMs can provide VDD pacing via mechanical sensing of atrial activity. While these devices can provide high-rates of AV synchrony, risk factors for poor mechanical sensing of atrial activity include a high E/A ratio and prior CABG surgery.[201] In persons who require extremely high degrees of AV synchrony, transvenous pacing or dedicated modular leadless PMs may be preferable.

Leadless technologies continue to rapidly evolve. Although this advancement is good for patients and clinicians, it can make the establishment of durable AUC challenging. Modular leadless PMs capable of providing DDD pacing were approved by the FDA and became available after these AUC were developed and validated. Thus, the criteria do not explicitly provide guidance on their use. In general, use of modular leadless PM devices should also be guided by the anticipated frequency of RV pacing, baseline ventricular function, and longevity/device replacement considerations. Future iterations of leadless PMs will likely expand pacing options. Randomized clinical trials will be critical to help define optimal implant strategies and help inform patient selection.

Section 12: Conduction System Pacing (HBP or Left Bundle Area Pacing)

Assumptions and Considerations

- For patients with LVEF ≤35% who are on optimal GDMT for ≥3 months, patient would be a candidate for an ICD (unless older or frail patient, etc).
- If the patient is not an ICD candidate, then patients have indications for a permanent PM.
- It is assumed that a backup pacing RV lead is available, if the operator feels it is necessary.

In patients with permanent PM indications who are undergoing dual-chamber PM implantation, placement of a lead intended to capture the AV conduction system (eg, the His bundle or infra-Hisian conduction system, such as the left bundle) may provide more physiological ventricular activation than placement of a lead inserted into RV myocardium alone. Observational studies suggest that CSP may improve outcomes with regard to ventricular function compared with that of RV pacing,[202,203] although HBP may occur at the possible expense of higher pacing thresholds or lower sensing.[120,173]

CRT delivered via a CS LV branch or the epicardium has been shown in multiple randomized, controlled studies to improve outcomes in patients with HF and delayed LV activation (wide QRS duration). Data are only recently emerging on the following: 1) whether His bundle or CSP provides equivalent or superior results as CRT pacing via a CS LV branch or the epicardium[120]; 2) whether non-responders to CRT should be changed to CSP, perhaps in conjunction with CS/LV pacing; 3) whether CSP should be

attempted first prior to CS/LV pacing in CRT candidates[120,173]; 4) whether CSP should be attempted instead of RV myocardial pacing in all patients receiving dual-chamber pacing; 5) the role of LV endocardial pacing (via a separate device implanted in the LV or leads inserted through the septum from the RV that may provide physiological pacing by capturing the left sided His-Purkinje system but may or may not require anticoagulation); and 6) the role of CSP for those with unfavorable CS anatomy, failed or suboptimal CRT implants, or CRT nonresponders.

The 2018 ACC/AHA/HRS Guideline on the Evaluation and Management of Patients With Bradycardia Cardiac Conduction Delay states that in patients with AV block and indications for permanent pacing with LVEF 36% to 50%, it is reasonable to choose pacing techniques providing more physiological ventricular activation (eg, with CRT, HBP) vs RV pacing to prevent HF with a Class IIa recommendation, LOE B-NR if expected ventricular pacing is >20% to 40% and C-limited data (C-LD) if expected ventricular pacing is <20% to 40%.[6] In patients with AV block at the level of the AV node with permanent pacing indications, HBP may be considered with a Class IIb recommendation, LOE B-NR. The "2021 ESC Guidelines on Cardiac Pacing and Cardiac Resynchronization Therapy" also include Class II recommendations for HBP.[8]

A systematic review for these guidelines analyzed 8 studies that compared BiV (4 studies) or HBP (4 studies) compared with RV pacing in patients with LVEF >35%.[204] Both methods appeared to mitigate structural and functional effects of RV pacing, particularly in patients with AF and rapid rates who underwent AV node ablation and in patients with LVEF 36% to 52%. LVEF was higher and NYHA functional class lower in patients with HBP compared with that of RV pacing (3 studies). In an observational study of all patients requiring permanent pacing, excluding CRT or prior CIEDs, at 2 sister hospitals from October 2013 to December 2016, one hospital placed RV pacing leads in 433 patients and the other hospital attempted HBP leads in 332 patients (successful in 92% of cases).[205] The primary outcome of death, HF hospitalization, or upgrade to BiV pacing was lower in the hospital attempting HBP leads (HR: 0.71; $P = 0.02$). Secondary outcomes of HF hospitalization were lower in the HBP hospital (HR: 0.633; $P = 0.02$) with a trend toward lower all-cause mortality (HR: 0.728; $P = 0.058$). In another study from 2011 of implants at these hospitals with long-term follow-up, pacing thresholds at 5 years were 0.84 ± 0.4 V with RV pacing compared with that of 1.62 ± 1.0 V with HBP, and sensed R waves 13.3 ± 5.7 mV with RV leads and 7.2 ± 5.2 mV with HBP leads.[206] In this study, LVEF did not significantly change with HBP but was lower with RV pacing ($P = 0.002$), including with patients with ventricular pacing >40%.

Small, randomized studies have been reported addressing HBP vs BiV pacing for CRT. In a single-blind, randomized crossover study of HBP vs BiV pacing in 29 CRT patients, HBP and LV leads were connected with the LV port via a Y-adapter and patients randomized to HBP or BiV pacing with crossover at 6 months.[207] In total, 75% achieved QRS narrowing at implant. Twelve patients completed crossover analysis at 1 year. Both pacing modes improved QOL, NYHA functional class, 6MWT, and LVEF. A small randomized trial, His-SYNC (His Bundle Pacing Versus Coronary Sinus Pacing for Cardiac Resynchronization Therapy), randomized 41 CRT-indicated patients to HBP CRT vs CS BiV pacing CRT.[120] Crossovers were mandated for the HBP arm, if HBP failed to achieve 20% QRS narrowing or QRS width ≤130 ms, or if there were high pacing thresholds >5 V @ 1 ms. Crossovers were permitted for CS BiV pacing if there was inability to place an adequate LV lead. Placement in the anterior interventricular or middle cardiac vein was discouraged. Significant reduction in QRS duration reached statistical significance in the His-CRT arm ($P = 0.002$) with a trend seen in the BiV-CRT arm ($P = 0.11$). Median change in LVEF was 5.2% in the BiV-CRT arm and 9.1% in the His-CRT arm (not significant).

The use of HBP as an alternative to failed CS/LV or nonresponsive CRT patients has been studied in small series to date. In a small study 16 patients in whom LV/CS leads were not achievable underwent HBP that corrected conduction disturbances in 13 (81%), although the lead could not be fixed in 4; the remaining 9 patients had successful resynchronization by HBP with improvements in LV function and functional class.[120] In another study of 106 patients, HBP was successful in 90% with improvements in QRS narrowing, LVEF, and NYHA functional class during a mean follow-up time of 14 months.[208] Lead complications occurred in 7 patients. Although limited in sample size, both studies supported use of HBP as an alternative to failed or nonresponsive CRT.

Results from LBB pacing using an HBP lead inserted deeper into the interventricular septum has been reported in nonrandomized studies.[209,210] In an observational study of 74 patients with HF and typical LBBB indicated for pacing, HBP leads were implanted if LBBB correction threshold was acceptable (<3.5 V @ 0.5 ms or 3.0 V @ 1.0 ms). LBBB correction was acutely achieved in 97.3%, and 75.7% received a permanent HBP lead; the remainder did not due to no LBB correction, high thresholds, or fixation failure. During a median follow-up of 37 months, among the 30 patients with permanent HBP leads completing 3-year follow-up, significant improvements in LVEF (32.4 ± 8.9% to 55.9 ± 10.7%; $P < 0.001$), LV end-systolic volume (137.9 ± 64.1 mL to 52.4 ± 32.6 mL; $P < 0.001$) and NYHA functional class ($P < 0.001$) were observed with stable thresholds of about 2.29 ± 0.92 V/0.5

TABLE 12.1 Conduction System Pacing (His Bundle Pacing or Left Bundle Branch Area Pacing)

Indication	Appropriate Use Score (1-9) His Bundle Pacing or Left Bundle Area Pacing		
	LVEF ≤35%	LVEF 36%-50%	LVEF >50%
Sinus Node Dysfunction; Anticipated Pacing Frequency: Less Than Substantial RVP*			
318. ■ Sinus node dysfunction, intact AV conduction, and a normal QRS	M (4)	M (4)	R (2)
319. ■ Sinus node dysfunction, LBBB	M (6)	M (6)	M (4)
320. ■ Sinus node dysfunction, RBBB	M (5)	M (4)	R (3)
321. ■ Sinus node dysfunction, IVCD (≥120 ms)	M (5)	M (4)	R (3)
Sinus Node Dysfunction; Anticipated Pacing Frequency: Substantial RVP*			
322. ■ Sinus node dysfunction, first-degree AV block (>250 ms), normal QRS	A (7)	A (7)	M (5)
AV Block; Anticipated Pacing Frequency: Substantial RVP*			
323. ■ Second-degree AV block, Mobitz type I, narrow QRS	A (7)	M (6)	M (5)
324. ■ Second-degree AV block, Mobitz type II, wide QRS	A (7)	A (7)	M (6)
325. ■ Intermittent third-degree AV block	A (7)	M (6)	M (5)
326. ■ Third-degree AV block, narrow junctional escape rhythm	A (7)	A (7)	M (5)
327. ■ Third-degree AV block, wide complex ventricular escape rhythm	A (7)	A (7)	M (6)
328. ■ Third-degree AV block, no escape rhythm	A (7)	A (7)	M (6)
329. ■ Patient undergoing AV junction ablation	A (7)	A (7)	M (6)
Failed CRT or Nonresponder; Anticipated Pacing Frequency: Substantial RVP*			
330. ■ Failed CRT CS/LV lead implantation	A (8)	A (7)	
331. ■ CRT nonresponders with LBBB	A (8)	A (7)	
332. ■ CRT nonresponders with RBBB	M (6)	M (6)	
333. ■ CRT nonresponders with IVCD	M (6)	M (6)	
Specific Scenarios; Anticipated Pacing Frequency: Substantial RVP*			
334. ■ Atrial fibrillation with slow ventricular response	A (7)	A (7)	M (5)
335. ■ Sinus rhythm with long first-degree AV block (eg, PR >300 ms)	A (7)	M (6)	M (5)

*Less than substantial RVP refers to anticipated or actual pacing <20%-40%, while substantial RVP refers to anticipated or actual pacing ≥20%-40%. Substantial RVP may occur due to second- or third-degree AV block or first-degree AV block with very prolonged PR intervals.

A = Appropriate; AV = atrioventricular; CRT = cardiac resynchronization therapy; IVCD = intraventricular conduction delay; LBBB = left bundle branch block; LV = left ventricular; LVEF = left ventricular ejection fraction; M = May Be Appropriate; R = Rarely Appropriate; RBBB = right bundle branch block; RVP = right ventricular pacing.

ms. In a prospective nonrandomized study of 100 patients requiring pacing for bradycardia or HF indications, LBBAP was successful in 93%; baseline and paced QRS duration was 133 ± 35 ms and 136 ± 17 ms, respectively. Subsequent larger registry studies of LBB area pacing, including a registry with 703 patients, have reported lower mortality, HF hospitalizations, or upgrade to BiV pacing compared with that of RV pacing.[211] A large randomized clinical trial in CRT candidates has begun, comparing CSP with BiV (NCT05650658).

Table 12.1 includes scenarios in which CSP with HBP or LBBAP might be considered. The scenarios explore whether more physiological pacing via the His bundle or LB branch might be comparable or advantageous to RV or BiV pacing. The implantation of CSP leads should be considered in the context of outcomes and performance data, the availability of ventricular pacing avoidance algorithms that could minimize the need for ventricular pacing and for CRT candidates the long-term experience and availability of randomized outcomes data.

Section 12 Results and Discussion

The panel determined that CSP, encompassing HBP or LBBAP, is Appropriate or May Be Appropriate for patients undergoing PM implantation anticipated to require *substantial (>20% to 40%) RV pacing*. In these situations, with patients expected to require substantial RV pacing, CSP was deemed Appropriate in patients with LVEF ≤35%. CSP is also Appropriate for patients expected to require substantial RV pacing with LVEF 36% to 50% and sinus node dysfunction, AV blocks, or for AF with slow ventricular response or AV junction ablation, with the exceptions that CSP May Be Appropriate in patients with narrow QRS and Mobitz type I second-degree AV

block, intermittent third-degree AV block, or sinus rhythm with long first-degree AV block. In comparison, cardiac physiological pacing guidelines[6] gave Class IIa or IIb and no Class I recommendations for CSP in these situations, particularly for patients with LVEF ≤35% and LBBB, where CRT received Class Ia (A) and CSP Class IIa (C-LD) recommendations, given the strong randomized clinical trial evidence base for improved outcomes, including mortality benefits, with CRT and only small or ongoing randomized trials for CSP.

For scenarios where anticipated RV frequency is expected to be *less than substantial* (<20%-40%), the level of appropriateness for CSP is lower than for situations in which substantial pacing is expected. Here, CSP May Be Appropriate for some patients with LVEF ≤50% and sinus node dysfunction but Rarely Appropriate for LVEF >50%, unless there is LBBB where CSP May Be Appropriate. In contrast, the cardiac physiologic pacing guidelines designated a Class IIb (C-LD) designation, where CSP may be reasonable in patients with LVEF 36% to 50% or >50%.

CSP was also deemed Appropriate for patients requiring CRT but who failed optimal CRT CS/LV lead implantation or who have LBBB but failed to respond to CRT. If effective CRT cannot be achieved, cardiac physiologic pacing guidelines designated for CSP a Class IIa recommendation for patients with LBBB, LVEF ≤35% and 2b (C-LD) recommendation for non-LBBB and QRS ≥150 ms. CSP was less certain for CRT nonresponders with RBBB or IVCD, where CSP May Be Appropriate. Here for non-LBBB, QRS duration 120-149 ms, LVEF ≤35%, and NYHA functional class III or IV HF, cardiac physiologic pacing guidelines gave CSP a Class IIb (C-LD) recommendation.

There continues to be rapid advancements in CSP. The writing group recognizes that these indications may change with time and continued improvements in technology as well as availability of results from large randomized clinical trials evaluating CSP in various cohorts.

7. DISCUSSION

Appropriate use documents are intended to inform clinicians, payers, and health policymakers about the reasonable use of technologies and procedures to improve patient symptoms and outcomes, often providing additional guidance in areas where there may be gaps in knowledge or lower levels of evidence. This AUC document summarizes the assessed levels of appropriateness for a variety of clinical scenarios involving the implantation of CIEDs, including the following: 1) ICDs implantation for secondary prevention indications; 2) ICD implantation for primary prevention indications; 3) primary prevention ICD implantation in the setting of specific comorbidities; 4) elective ICD generator replacement; 5) choice of dual-chamber ICD implantation (as opposed to single-chamber devices); 6) total S-ICD implantation; 7) CRT implantation; 8) ICDs in the setting of LVADs; 9) ICD implantation after heart transplantation; 10) CCM; 11) leadless pacing and bradycardia pacing; and 12) CSP. These AUC are meant to act as a guide in clinical decision making regarding appropriate patient selection and/or timing of device implantation; however, it is important to acknowledge that patients may not always neatly fit within a given clinical scenario and that clinical judgment is always necessary for assessing device implantation for individual patients.

7.1. Clinical Judgment and the Understanding of AUC Ratings to Improve Care

The AUC should be used in conjunction with published practice guidelines and are meant to provide additional guidance concerning the decision to implant CIEDs in a variety of clinical scenarios that may be represented in the guidelines, often providing additional assistance in areas where there are gaps in the guidelines. This AUC document also highlights scenarios where these conditions and recommendations may be modified by patient comorbidities or limitation of life expectancy due to coexisting diseases, as well as scenarios where newer technology might also be considered despite limited currently available evidence. The scenarios included in this document do not encompass all possible clinical situations that may be encountered in practice. Instead, the goal was to focus on the most common clinical situations encountered in practice where specific implanted arrhythmia and HF devices may be considered. The goal of rating appropriateness is to help inform clinical decision making, particularly in areas where there may be “gaps” in the guidelines, rather than to establish rules by which decisions should be made in clinical practice. These criteria should serve as a “guide,” rather than as a list of “do” or “do not do” specifications.

Clinical decision making is complex, especially when trying to assess clinical benefit and potential long-term consequences of living with an implanted device. Although the appropriate use ratings reflect a general assessment of when ICD, CRT, or PMs may or may not be useful for specific patient populations, clinicians are still expected to use clinical judgment in determining whether CIED implantation is indicated for an

individual patient and shared decision making should always be utilized to incorporate individual patient values and preferences. It is important to recognize that a May Be Appropriate recommendation may represent either the lack of sufficient data to inform the decision or conflicting data regarding the benefit of device implantation, often advocating for additional clinical trials or studies to better inform decision making in the future. In addition, attribution of Appropriate to a clinical scenario does not necessarily indicate that implantation is mandatory, rather that it is reasonable given existing data. There may be some clinical scenarios in which the use of ICD, CRT, or other pacing devices for an indication considered Appropriate does not always represent reasonable practice or may not align with a patient's values and preferences.

AUC should be considered in concert with the guidelines. The indications in AUC documents are more granular and cover more specific patient scenarios that are not specifically addressed in guidelines. Where there is overlap with the device-based therapy guidelines, the ratings are in general consistent with guideline recommendations. Overall, criteria that have been deemed Appropriate or May Be Appropriate in these scenarios often met Class I, IIa, or IIb criteria in guideline or consensus documents; were supported by a critical mass of existing data; or were deemed by the rating panel to meet sufficient clinical judgment to be reasonable and appropriate.

Finally, there are differences in the current AUC for CIED implantation and previous AUC documents related to other topics such as imaging or catheterization. The decision to implant a device results in long-term, specialized follow-up and carries anticipated long-term inpatient and outpatient costs and adverse events that may accumulate with time.

7.2. Use of AUC to Provide Guidance

This AUC document has been designed to provide guidance related to CIED implantation. As with prior AUC documents, it is important to emphasize that an Appropriate rating does not mean that a given procedure must be performed, nor does a Rarely Appropriate rating mean a procedure should never be performed in a patient who fits the scenario(s) listed in this document. Rather, a procedure with an Appropriate rating should be seen as an option that would be reasonable to perform if the information obtained may be useful in managing the patient. Similarly, for a Rarely Appropriate rating, there may be additional clinical circumstances that dictate the need for treatment. It is recommended that such circumstances be documented clearly by the ordering clinician.

It is the intent of this AUC document to address good medical practice, independent of payment. Some of the scenarios that are rated as May Be Appropriate or Rarely Appropriate by the AUC may not currently qualify for insurance coverage. It is important to recognize that the categories May Be Appropriate and Rarely Appropriate should not be considered as grounds for denial of insurance coverage or payment for a particular procedure, as clinician judgment is essential for determining which procedure is best for a specific patient. For patients, clinicians, and insurers, these distinctions are of critical importance because commitment to patient-centered care may warrant implantation of a device appropriate for the individual patient's situation, but it may not fit precisely into a covered indication as defined by coverage policy and requires use of best clinical judgment. However, it is possible that appropriate use documents could serve as an additional resource to support coverage in the future.

8. CONCLUSIONS

This AUC document represents the current understanding of the clinical utility of arrhythmia device implantation in clinical practice as measured by clinicians with a variety of backgrounds and areas of expertise. It is the goal that these criteria will help provide a guide to inform medical decisions and help clinicians and stakeholders understand areas of consensus as well as uncertainty, while identifying areas where there are gaps in knowledge that warrant additional investigation.

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KEY WORDS ACC appropriate use criteria, cardiac resynchronization therapy, implantable cardioverter-defibrillator, pacing

APPENDIX 1. WRITING GROUP, RATING PANEL, AND EXTERNAL REVIEWERS—RELATIONSHIPS WITH INDUSTRY AND OTHER ENTITIES (COMPREHENSIVE)—2025 APPROPRIATE USE CRITERIA FOR IMPLANTABLE CARDIOVERTER-DEFIBRILLATORS, CARDIAC RESYNCHRONIZATION THERAPY, AND PACING

Participant	Employment	Representing	Consultant	Speakers Bureau	Ownership/ Partnership/ Principle	Personal Research	Institutional, Organizational, or Other Financial Benefit	Expert Witness
			WRITING GROUP					
Andrea M. Russo, *Co-Chair*	Cooper Medical School of Rowan University—Professor of Medicine; Cooper University Health Care—Academic Chief, Division of Cardiology; Director of Electrophysiology and Arrhythmia Services; Director of CCEP Fellowship	ACC	■ Abbott ■ AtriCure ■ Bayer Healthcare Pharmaceuticals ■ Biosense Webster ■ Biotronik ■ Bristol Myers Squibb/Pfizer ■ Boston Scientific ■ Medtronic* ■ PaceMate ■ Sanofi	None	None	■ Abbott ■ Bayer ■ Medtronic* ■ Boston Scientific*	■ ABIM ■ Boston Scientific (UNTOUCHED)† ■ Kestra (ACE-DETECT)† ■ MediLynx (Cryptogenic stroke study, cryptogenic stroke and subclinical atrial fibrillation study)† ■ Medtronic (DEFINE-AF)† ■ UpToDate	None
Milind Y. Desai, *Co-Chair*	University of Oxford—Honorary Professor of Cardiovascular Medicine; Cleveland Clinic HCM Center—Director	ACC	■ Bristol Myers Squibb* ■ Caristo Diagnostics ■ Edgewise Therapeutics ■ Tenaya Therapeutics* ■ Viz.ai	None	None	None	None	None
Monika M. Do, *Vice-Chair*	Vanderbilt University School of Nursing—Assistant Professor	ACC	None	None	None	None	None	None

APPENDIX 1. CONTINUED

Participant	Employment	Representing	Consultant	Speakers Bureau	Ownership/ Partnership/ Principle	Personal Research	Institutional, Organizational, or Other Financial Benefit	Expert Witness
Javed Butler	University of Mississippi—Professor of Medicine; Baylor Scott and White Health—Senior Vice President	HFSA	■ Abbott Laboratories ■ American Regent ■ Applied Therapeutics ■ AstraZeneca* ■ Bayer* ■ Boehringer Ingelheim* ■ Cardiac Dimensions ■ Cardior ■ CVRx* ■ Cytokinetics ■ Daxor‡ ■ Edwards Lifesciences* ■ Element Science* ■ Eli Lilly and Company* ■ FIRE1‡ ■ Imbria ■ Impulse Dynamics* ■ Innolife ■ Inventiva ■ Lexicon ■ LivaNova ■ Medtronic ■ Merck* ■ Novartis* ■ Novo Nordisk* ■ Occlutech ■ Pharmacosmos ■ Pfizer ■ Roche ■ Sequana Medical* ■ SQ Innovation ■ Tenex Health ■ Tricog Health ■ Vifor*	■ Novartis	None	None	■ Amgen ■ Bristol-Myers Squibb Company ■ Cardiometabolic Centers Alliance‡ ■ *Circulation*‡ ■ *European Heart Journal*‡ ■ *European Journal of Heart Failure*‡ ■ G3 Pharmaceutical‡ ■ *JACC Heart Failure*‡ ■ *Journal of the American College of Cardiology** ■ Medscape*	None

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APPENDIX 1. CONTINUED

Participant	Employment	Representing	Consultant	Speakers Bureau	Ownership/ Partnership/ Principle	Personal Research	Institutional, Organizational, or Other Financial Benefit	Expert Witness
Mina K. Chung	Cleveland Clinic—Professor of Medicine	ACC	■ ABIM* ■ ACC-Kansas City Cardiometabolic Health Congress ■ Cedars-Sinai Medical Center ■ Geisinger Health Systems/Geisinger Medical Center, Dept of Medicine ■ Kansas City Heart Rhythm Symposium ■ Northwell Health ■ University of Chicago ■ University of Pittsburgh Medical Center	None	None	None	■ Abbott (SyncAV Post-Market Trial)† ■ AHA* ■ Boston Scientific (NEwTON AF, APPRAISE ATP, INTERRUPT AF, WATCH RWE)† ■ HRS‡ ■ France ANR ■ Hamilton Health Sciences, Population Health Research Institution (ARTESIA)† ■ Impulse Dynamic (INTEGRA-D Study)† ■ Myocardial Solutions (Assessment of left ventricular volumes and strain and assessment of valvular lesions using 2- and 3-dimensional echocardiography and cardiac MRI, a correlation study)† ■ NIH* ■ Trustees of the University of Pennsylvania (RAAFT-3 Trial)† ■ UpToDate	None
Andrew E. Epstein	Philadelphia VA Hospital—Chief, Division of Cardiology	HRS	■ Abbott ■ HeartBeam ■ ZOLL	None	None	■ Medtronic*	■ AHA (Editorial Board)* ■ Boston Scientific (DSMB) ■ MediaSphere Medical	■ 2020 Patient death after pacemaker ■ 2019 Patient died awaiting ICD
Maya E. Guglin	Indiana University—Professor of Medicine; Director of HF/Transplant/MCS	ACC	None	None	None	None	None	None
Wayne C. Levy	University of Washington—Professor of Medicine and Cariology; Medical Director	ACC	■ Impulse Dynamics ■ Medtronic* ■ PharmaIN‡	None	None	■ Medtronic*	■ Abbott* ■ Baim Institute for Clinical Research* ■ Cardiac Dimensions ■ EBR Systems* ■ Respicardia ■ University of Washington‡	None
Jonathan P. Piccini	Duke University of Medicine—Professor of Medicine; Director of Cardiac Electrophysiology Section	ACC	■ Abbott* ■ AbbVie ■ BIOTRONIK ■ ElectroPhysiology Frontiers* ■ Medtronic* ■ Milestone ■ Philips* ■ Sanofi Aventis* ■ UpToDate*	None	None	■ Abbott Laboratories* ■ AHA* ■ Bayer* ■ Boston Scientific* ■ iRhythm Technologies* ■ Philips*	■ Element Science (DSMB)* ■ LivaNova*	None

APPENDIX 1. CONTINUED

Participant	Employment	Representing	Consultant	Speakers Bureau	Ownership/ Partnership/ Principle	Personal Research	Institutional, Organizational, or Other Financial Benefit	Expert Witness
			RATING PANEL					
Nicole M. Bhave	University of Michigan—Professor of Medicine	ACC–Moderator	ACCF	None	None	Rednvia	None	None
Amrut V. Ambardekar	University of Colorado Medicine—Associate Professor of Medicine and Cardiology; Director Cardiac Transplant and Cardiac Amyloidosis Program	ACC	None	None	None	None	■ Eidos (ATTRIBUTE-CM Trial)† ■ Ionis (CardioTransform Study)†	None
Nancy C. Berg	Allina Health United Hospital—Adult Care Nurse Practitioner	ACC	None	None	None	None	None	None
Kenneth C. Bilchick	University of Virgina—Professor of Medicine	AHA	None	None	None	■ ACC* ■ AHA* ■ NIH*	■ Medtronic (AdaptivCRT)† ■ Milestone (MSP-2027-1109)† ■ St. Jude Medical (Multipoint Pacing Post-Market Study)†	None
G. William Dec Jr	Massachusetts General Hospital—Chief (Emeritus) Cardiology Division, Roman W. DeSanctis Professor of Medicine	ACC	None	None	None	None	None	None
Rakesh Gopinathannair	Kansas City Heart Rhythm Institute—Cardiac EP Lab Director; Professor of Medicine	ACC	■ Abbott Medical* ■ Academy for Continued Health-care Learning ■ AltaThera	None	None	None	■ PaceMate	None
Janet K. Han	VA Greater Los Angeles Healthcare System—Associate Professor of Medicine, Cardiac Electrophysiologist	ACC	■ iRhythm Technologies ■ Medtronic ■ Vector Remote Care	None	None	None	■ AliveCor‡	None
Liviu Klein	University of California, San Francisco—Director, Advanced Heart Failure Comprehensive Care Center	HFSA	■ Abbott Laboratories* ■ Abiomed ■ Boston Scientific ■ Edwards Lifesciences	None	None	None	■ Ancora (CORCINCH-HF)† ■ Axon (REBALANCE-HF)† ■ Cordio (CORDIO)† ■ Edwards Lifesciences (ALT FLOWI)† ■ Medtronic* ■ Nuwellis (REVERSE HF)† ■ Procyrion (DRAIN HF)† ■ Revamp Medical (DORAYA HF)† ■ V-WAVE (RELIEVE-HF)†	None
Rachel J. Lampert	Yale Medical School—Professor of Medicine	HRS	None	None	None	None	■ Medtronic (Product Surveil-lance Registry)†	None

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APPENDIX 1. CONTINUED

Participant	Employment	Representing	Consultant	Speakers Bureau	Ownership/ Partnership/ Principle	Personal Research	Institutional, Organizational, or Other Financial Benefit	Expert Witness
Gurusher S. Panjrath	George Washington University Medical Faculty Associates—Director, Heart Failure and Mechanical Support Program	ACC	■ CVRx*	■ Pfizer*	None	None	■ Ionis (TTR Transform)†	None
Ryan R. Reeves	University of California, San Diego—Associate Professor of Medicine	SCAI	■ MaxWell Biomedical	None	None	None	■ Abbott Vascular (ILUMIEN IV)† ■ Corindus (Precision GRX Registry)† ■ CRF (TAVR UNLOAD)† ■ CSI (ECLIPSE)† ■ Population Health Research Institute (COMPLETE)† ■ SCAI‡ ■ University of California, San Diego‡	■ 2020, Acute coronary syndrome, Plaintiff ■ 2019, Left atrial appendage occlusion, Plaintiff ■ 2019, Acute coronary syndrome, Plaintiff
Danita Marie Yoerger Sanborn	Massachusetts General Hospital—Assistant Professor	ASE	None	None	None	None	None	None
Lynne W. Stevenson	Vanderbilt University Medical Center—Professor of Medicine, Director of Cardiomyopathy Program; Director Training Program Advanced Heart Failure Transplant	HFSA	■ ABIM* ■ Novartis-EP	None	None	■ NHLBI*	■ Abbott‡ ■ Abbott Medical ■ Biotronik ■ Boston Scientific ■ Bristol-Myers Squibb Company‡ ■ Endotronix‡ ■ Endotronix (ProACTIV III)† ■ Johnson & Johnson ■ NHLBI	None
Quynh A. Truong	Weill Medicine Cornell—Professor	SCCT	None	None	None	None	None	None
Paul D. Varosy	Department of Veteran Affairs, University of Colorado—Deputy National Program Director for Cardiology; Professor of Medicine	ACC	None	None	■ Heart Rhythm Clinical Research Solutions/ 3PH Alliance‡	■ Principal Investigator, Career Development Award, Co-investigator Veteran Affairs Merit Review Grant*	■ AHA, Guest Editor, *Circulation*; *Circulation: Arrhythmia and Electrophysiology*; *Circulation: Cardiovascular Quality and Outcomes*‡ ■ Outpatient Endovascular Interventional Society‡	None

APPENDIX 1. CONTINUED

Participant	Employment	Representing	Consultant	Speakers Bureau	Ownership/ Partnership/ Principle	Personal Research	Institutional, Organizational, or Other Financial Benefit	Expert Witness
Todd C. Villines	University of Virginia Health System—Professor of Medicine, Division of Cardiovascular Medicine	ACC	None	None	None	None	None	None
Annabelle S. Volgman	Rush University—Professor of Medicine; Vice-Chair of Academic Affairs	ACC	■ Janssen ■ Pfizer ■ Sanofi*	None	None	None	■ Jannsen ■ Jannsen (LIBREXIA AF)† ■ Novartis (Novartis CTQJ230A12001)†	None
Karolina M. Zareba	The Ohio State University Wexner Medical Center—Associate Professor	SCMR	None	None	None	None	None	None
			REVIEWERS					
Sana Al-Khatib	Duke University—Professor of Medicine	ACC	None	None	None	None	■ AHA*	None
Charles I. Berul	Children's National Medical Center—Division Chief of Pediatric Cardiology	AHA	None	None	None	None	None	None
Ulrika Birgersdotter-Green	University of California, San Diego—Clinical Professor, Medicine	ACC	■ Abbott Laboratories* ■ Biotronik ■ Boston Scientific ■ Medtronic ■ Philips	None	None	None	None	None
Kristen Bova Campbell	Duke University Hospital—Clinical Pharmacist	ACC-CV Team Council	■ Wolters Kluwer	None	None	None	■ HRS	None
Richard J. Czosek	Cincinnati Children's Hospital Medical Center—Director, Electrophysiology Co-Director, Heart Institute Research Core Professor, UC Department of Pediatrics	AHA	None	None	None	None	None	None
Cynthia Dougherty	University of Washington School of Nursing—Spence Endowed Professor	AHA	None	None	None	None	None	None
Taya V. Glotzer	Hackensack University Medical Center—Professor of Medicine	HRS	■ Abbott Laboratories ■ Boston Scientific ■ Medtronic	None	None	None	■ Boehringer Ingelheim (GLORIA-AF)† ■ Medtronic ■ Medtronic (STROKE AF)† ■ Medtronic (REVEAL AF)† ■ Population Health Research Institute DBCVSRI (ARTESIA)† ■ St. Jude ■ St. Jude (TACTIC AF)†	None

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APPENDIX 1. CONTINUED

Participant	Employment	Representing	Consultant	Speakers Bureau	Ownership/ Partnership/ Principle	Personal Research	Institutional, Organizational, or Other Financial Benefit	Expert Witness
Michael R. Gold	Medical University of South Carolina—Professor of Medicine	HRS	■ Abbott Laboratories ■ Boston Scientific* ■ CVRx ■ EBR Systems ■ HRS* ■ Springer*	None	None	■ Boston Scientific* ■ Medtronic	None	None
Stephen Greene	Duke University Medical Center—Associate Professor of Medicine	HFSA	■ Amgen* ■ AstraZeneca* ■ Bayer Healthcare Pharmaceuticals* ■ Boehringer Ingelheim* ■ Corcept Therapeutics* ■ CSL Vifor* ■ Cytokinetics* ■ Lexicon* ■ Merck* ■ Novo Nordisk* ■ Otsuka* ■ PhamaIN* ■ Roche Diagnostics* ■ Sanofi* ■ scPharmaceuticals* ■ Tricog Health* ■ Urovant Sciences	None	None	■ AstraZeneca‡ ■ Bristol-Myers Squibb Company* ■ Bristol-Myers Squibb‡ ■ Novartis* ■ Pfizer*	None	None
Michael S. Kiernan	Tufts Medical Center—Associate Chief, Division of Cardiology	HFSA	None	None	None	None	■ Endotronix ■ Endotronix (ProACTIVE)† ■ EvaHeart (Evaheart)† ■ preCARDIA (VENUS-HF)†	■ 2018 Cardiogenic shock, Plaintiff ■ 2024 Perioperative evaluation, Defendant*
Igor Klem	Duke University—Associate Professor	SCMR	■ Bayer*	None	None	■ Medtronic*	None	None
Dan Matlock	University of Colorado—Professor	AGS	None	None	None	■ ACCF* ■ Colorado Health Foundation* ■ NIH* ■ Patient-Centered Outcomes Research Institute*	None	None

APPENDIX 1. CONTINUED

Participant	Employment	Representing	Consultant	Speakers Bureau	Ownership/ Partnership/ Principle	Personal Research	Institutional, Organizational, or Other Financial Benefit	Expert Witness
Debabrata Mukherjee	Texas Tech University Health Sciences Center at El Paso—Chairman, Department of Internal Medicine	SCAI	■ ACC*	None	None	None	■ NIH‡	None
Parin J. Patel	Ascension St. Vincent Heart Center—Director, Electrophysiology Laboratory	ACC-EP Council	■ Biosense Webster ■ Boston Scientific	None	None	None	None	None
Satish R. Raj	University of Calgary & Alberta Health Services—Professor of Cardiac Sciences	HRS	■ Antag Therapeutics ■ argenx ■ Elsevier ■ Regeneron ■ STAT Health ■ Theravance	None	None	■ Dysautonomia International* ■ Long COVID Web* ■ Standing Up to POTS*	■ Canadian Cardiovascular Society‡ ■ Theravance (Phase 3 Clinical Effect of TD-9855 for Treating snOH in Subjects With Primary Autonomic Failure)†	None
Heather M. Ross	Arizona State University and HonorHealth—Clinical Associate Professor and Nurse Practitioner	ACC-CV Team Council	None	None	None	None	None	None
Sangeeta Shah	VCU Health System—Medical Director, Adult Congenital Heart Disease	ASE	None	None	None	None	None	None
Sarah Slone	Johns Hopkins University—Postdoctoral Fellow	ACC-CV Team Council	None	None	None	None	None	None
Katherine C. Wu	Heart and Vascular Institute at Johns Hopkins Medicine—Associate Professor of Medicine	SCMR	None	None	None	None	None	None
Erica Zado	Hospital of the University of Pennsylvania—Physician Assistant	ACC-CV Team Council	None	None	None	None	None	None

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*Significant relationship.

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‡No financial benefit.

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