Sudden Cardiac Arrest (SCA) Prevention Treatment Algorithms

- Inpatient to Outpatient Transition
- ACE Inhibitors and/or ARBs
- Beta Blockers
- Aldosterone Antagonists
- Implantable Cardioverter Defibrillator Therapy (ICD Inpatient)
- Cardiac Resynchronization Therapy (CRT Inpatient)
- Anticoagulation Therapy in Patients with Atrial Fibrillation (Outpatient)
- Management of Volume Overload (Outpatient)
- Implantable Cardioverter Defibrillator (ICD Outpatient)
- Cardiac Resynchronization Therapy (CRT Outpatient)
- Device Therapy

Sudden Cardiac Arrest (SCA) Prevention Pathways and Tools Objectives

- **Facilitate** optimal care for post-MI and HF patients at risk for SCA
- **Educate** healthcare providers and patients about SCA and treatment options and increase awareness and patient access to diagnostics and lifesaving therapies
- **Promote** evidence-based, guideline-recommended medical and device therapy and increase guideline awareness and adoption among healthcare providers
- **Assist** hospitals and practices in closing treatment gaps by providing practical information, disease management, and communication tools to identify and treat patients at risk for SCA

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This clinical tool is not intended to replace individual medical judgment or individual patient needs.

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April 2007
Revised September 2008
Angiotensin-Converting Enzyme Inhibitor (ACEI)/Angiotensin Receptor Blocker (ARB)
Inpatient/Outpatient Treatment Algorithm

**Patients with heart failure and systolic dysfunction**
Asymptomatic, mild, moderate, or severe symptoms

**Start ACEI or ARB**
(with a diuretic if volume overload present)

**Dosage initiation and titration***

**Patient exclusion criteria**
**ACEIs:** ACEI allergy, angioedema, intolerable cough, moderate or severe aortic stenosis, shock, symptomatic hypotension, hyperkalemia (K⁺ > 5.5 mEq/L), bilateral renal artery stenosis, pregnancy
**ARBs:** ARB allergy, shock, symptomatic hypotension, hyperkalemia (K⁺ > 5.5 mEq/L), bilateral renal artery stenosis, pregnancy

Rapid up-titration to the target dose is recommended except when limited by borderline BP and/or renal function. For hospitalized patients, titration to target dose can often be accomplished during the inpatient stay.

**ACEIs/ARBs – Refer to table on back of card**

**Serum Cr may increase after addition of ACEI. If the increase plateaus or returns to baseline, maintain dose titration. If serum Cr continues to increase, slow titration rate. Adjust diuretic dose as needed. The diuretic dose should be the lowest that maintains euvoema.**

**Monitoring**
- Heart failure symptoms
- Serum K⁺
- Serum Cr/renal function
- BP
- Concomitant drug interactions
  - NSAIDs, COX-2 inhibitors
- Volume status/diuretic dose

**Serum K⁺ increases an average of 0.3 mEq/L on ACEI therapy. Adjust potassium supplementation, aldosterone antagonist, and potassium-containing salt substitutes as clinically indicated.**

**Note:** Careful consideration of patient characteristics and choice of drugs is warranted.

* For hospitalized patients previously treated with ACEI/ARB at the time of admission, therapy should be continued in the absence of contraindications.
<table>
<thead>
<tr>
<th>ACEIs</th>
<th>ARBs†</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Initial dose</strong></td>
<td></td>
</tr>
<tr>
<td>Captopril</td>
<td>6.25 mg tid</td>
</tr>
<tr>
<td>Enalapril</td>
<td>2.5 mg bid</td>
</tr>
<tr>
<td>Lisinopril</td>
<td>2.5-5 mg qd</td>
</tr>
<tr>
<td>Ramipril</td>
<td>2.5 mg qd</td>
</tr>
<tr>
<td>Trandolapril</td>
<td>1 mg qd</td>
</tr>
<tr>
<td>Quinapril</td>
<td>10 mg qd</td>
</tr>
<tr>
<td>Fosinopril</td>
<td>10 mg qd</td>
</tr>
<tr>
<td>Candesartan</td>
<td>4-8 mg qd</td>
</tr>
<tr>
<td>Valsartan</td>
<td>40 mg qd</td>
</tr>
<tr>
<td><strong>Titration steps</strong></td>
<td></td>
</tr>
<tr>
<td>(typically double dose at each step)</td>
<td></td>
</tr>
<tr>
<td>Captopril</td>
<td>12.5 mg tid</td>
</tr>
<tr>
<td>Enalapril</td>
<td>25 mg tid</td>
</tr>
<tr>
<td>Lisinopril</td>
<td>5 mg bid</td>
</tr>
<tr>
<td>Ramipril</td>
<td>5 mg qd</td>
</tr>
<tr>
<td>Trandolapril</td>
<td>5 mg qd</td>
</tr>
<tr>
<td>Quinapril</td>
<td>2 mg qd</td>
</tr>
<tr>
<td>Fosinopril</td>
<td>20 mg qd</td>
</tr>
<tr>
<td>Candesartan</td>
<td>40 mg qd</td>
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<tr>
<td>Valsartan</td>
<td>16 mg qd</td>
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<tr>
<td><strong>Target dose</strong></td>
<td></td>
</tr>
<tr>
<td>Captopril</td>
<td>50 mg tid</td>
</tr>
<tr>
<td>Enalapril</td>
<td>10 mg bid</td>
</tr>
<tr>
<td>Lisinopril</td>
<td>20 mg qd</td>
</tr>
<tr>
<td>Ramipril</td>
<td>10 mg qd</td>
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<tr>
<td>Trandolapril</td>
<td>4 mg qd</td>
</tr>
<tr>
<td>Quinapril</td>
<td>80 mg qd</td>
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<tr>
<td>Fosinopril</td>
<td>80 mg qd</td>
</tr>
<tr>
<td>Candesartan</td>
<td>32 mg qd</td>
</tr>
<tr>
<td>Valsartan</td>
<td>160 mg qd</td>
</tr>
</tbody>
</table>

† ARBs are most frequently used in place of ACEIs when side effects limit ACEI use (intolerable cough may occur in as many as 20% of patients receiving ACEIs).

Routine combined use of an ACEI, ARB, and aldosterone antagonist is not recommended for patients with current or prior symptoms of HF and reduced LVEF.

**Reference Sources**


Adapted, with permission, by the SCA Prevention Medical Advisory Team, from the IMPROVE HF toolkit. This is a general algorithm to assist in the management of patients. This clinical tool is not intended to replace individual medical judgment or individual patient needs. Refer to the manufacturers’ prescribing information and/or instructions for use for the indications, contraindications, warnings, and precautions associated with the medications and devices referenced in these materials.

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April 2007
Beta Blocker Inpatient/Outpatient
Treatment Algorithm

Patients with heart failure and systolic dysfunction
Asymptomatic, mild, moderate, or severe symptoms

Patient exclusion criteria
• Cardiogenic shock
• Unstable or decompensated heart failure
• Symptomatic hypotension
• Symptomatic bradycardia without a pacemaker
• Heart block > 1st degree without a pacemaker
• Severe reactive airway disease

Initiation and titration

Guideline Recommended Beta Blockers for HF

<table>
<thead>
<tr>
<th>Carvedilol</th>
<th>Sustained-release metoprolol succinate</th>
<th>Bisoprolol</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Initial dose</strong></td>
<td>3.125 mg bid</td>
<td>12.5-25 mg qd</td>
</tr>
<tr>
<td><strong>Titration steps</strong></td>
<td>6.25 mg bid  12.5 mg bid</td>
<td>50 mg qd  100 mg qd  150 mg qd</td>
</tr>
<tr>
<td><strong>Target dose</strong></td>
<td>25 mg bid</td>
<td>200 mg qd</td>
</tr>
</tbody>
</table>

If volume overload develops, continue BB unless:
• Cardiogenic shock
• Systemic hypotension
• Narrow pulse pressure
• Cold, clammy skin
• Rising BUN/serum Cr

Maintain diuretic at lowest dose necessary to maintain euvoelema.

If patient becomes orthostatic, reduce diuretic dose and/or stagger doses of ACEI/ARB and other medications that lower BP.

Patient Monitoring:
• Daily weight
• Symptoms of worsening heart failure
• BP, HR
• Diuretic dosage

Outpatient Monitoring
Recommend that patients compile daily weight log and notify their MD if weight increases 3-5 lbs or more in 1 week.

Outpatient Monitoring
Patients should notify MD if they develop symptomatic hypotension and/or bradycardia.
References
1 Beta blocker therapy initiation is recommended for patients with a recent decompensation of HF after optimization of volume status and successful discontinuation of IV diuretics and vasoactive agents, including inotropic support. Whenever possible, beta blockade should be initiated in the hospital setting at a low dose in stable patients prior to discharge.
2 Patients hospitalized with decompensated HF already treated with beta blocker therapy prior to hospitalization should continue on beta blocker therapy as long as they do not have any contraindications, are not in cardiogenic shock, and do not show signs of systemic hypoperfusion (altered mental status, narrow pulse pressure, cold or clammy skin, rising BUN/serum Cr). A temporary reduction of dose in this setting may be considered. Abrupt discontinuation should be avoided, if possible. If discontinued or reduced, beta blockers should be reinstated or the dose should be gradually increased before the patient is discharged.
3 ACC/AHA 2005 guidelines recommend using only those beta blockers proven to be effective in heart failure (carvedilol, sustained-release metoprolol succinate, and bisoprolol) at the doses studied in large clinical trials. If patient is currently on a beta blocker other than those listed, consider switching.
4 Applies to both outpatients and those hospitalized for heart failure.
5 Beta blocker titration steps are generally at 2-week intervals. BP and HR should be carefully monitored. If SBP is < 80 mmHg or HR is < 55 bpm, assess the dose and recheck patient carefully for signs of hypoperfusion. Recheck status as needed.
6 Patients who cannot achieve target dose of the beta blocker should be maintained on the highest tolerated dose.
7 For patients weighing > 85 kg, carvedilol 50 mg bid may be used.

Reference Sources

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Sponsored by Medtronic, Inc.
April 2007
Aldosterone Antagonist
Inpatient/Outpatient Treatment Algorithm

Patients with systolic dysfunction
Moderately severe to severe heart failure

Patients with systolic dysfunction
Post-AMI with heart failure and/or post-AMI with diabetes

Patient exclusion criteria:
• Serum K⁺ > 5.0 mEq/L
• Serum Cr > 2.5 mg/dL (men); > 2.0 mg/dL (women)
• Estimated Cr clearance < 30 mL/min
• Close patient monitoring cannot be ensured

Initiate and titrate
Spironolactone*
12.5 mg qd†
25 mg qd

Eplerenone
25 mg qd
50 mg qd

Closely monitor serum Cr and serum K⁺, check at:
• 3 days
• 1 week
• 1 month (x 3 months)
• As needed
Hyperkalemia may complicate treatment and lead to life-threatening arrhythmias, thus close monitoring is essential.

Routine combined use of an ACEI, ARB, and aldosterone antagonist is not recommended for patients with current or prior symptoms of heart failure and reduced LVEF.

* Switch to eplerenone if signs of gynecomastia.
† Start at 6.25 mg qd in patients at increased risk for hyperkalemia.

• Impaired renal function is a risk factor for hyperkalemia during treatment with aldosterone antagonists. The risk of hyperkalemia increases progressively when serum Cr > 1.6 mg/dL.
• Hyperkalemia risk is increased with concomitant use of higher doses of ACEIs or ARBs
• NSAIDs and COX-2 inhibitors should be avoided
• Potassium supplements should be discontinued or reduced
• Dehydration, by diarrhea or other causes, should be addressed emergently

Ongoing clinical trials are evaluating the benefit of aldosterone antagonists in patients with mild heart failure.
Reference Sources


Adapted, with permission, by the SCA Prevention Medical Advisory Team, from the IMPROVE HF registry toolkit.
This is a general algorithm to assist in the management of patients. This clinical tool is not intended to replace individual medical judgment or individual patient needs.
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April 2007
Implantable Cardioverter Defibrillator (ICD) Therapy
Inpatient Algorithm

Secondary prevention
- Congenital high risk of VT/VF
- Cardiac arrest due to VT/VF
- Sustained VT/VF, spontaneous or induced by EPS
- Hemodynamically disabling VT
- Syncope

Primary prevention
Patient on chronic optimal medical therapy prior to hospitalization

- LVEF ≤ 30%*
- LVEF 31-40%
- LVEF ≤ 35%*

Exclusion criteria/not indicated:
- NYHA Class IV† (unless eligible for CRT)
- Cardiogenic shock or hypotension
- CABG or PTCA within past 3 months
- Candidate for coronary revascularization
- Irreversible brain damage from pre-existing cerebral disease
- Other disease with survival < 1 yr

Refer for ICD evaluation during this hospitalization or schedule evaluation post-hospital discharge

Exclusion criteria/not indicated:
- NYHA Class IV† (unless eligible for CRT)
- Cardiogenic shock or hypotension
- CABG or PTCA within past 3 months
- Candidate for coronary revascularization
- Irreversible brain damage from pre-existing cerebral disease
- Other disease with survival < 1 yr

* Class I recommendation.
† Functional status as documented prior to current hospitalization while on chronic optimal medical therapy.
†† CMS coverage for primary prevention ICD implants: patients with nonischemic dilated cardiomyopathy (NIDCM) > 9 months, NYHA Class II and III heart failure, and measured LVEF ≤ 35%. Patients with NIDCM > 3 months and < 9 months, NYHA Class II or III heart failure, and measured LVEF ≤ 35% at this time are only covered by Medicare if these patients are enrolled in an FDA-approved category B IDE clinical trial, a trial under the CMS clinical trial policy, or the American College of Cardiology National Cardiovascular Data Registry (ACC-NCDR).
Reference Sources


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Sponsored by Medtronic, Inc.
April 2007
Revised September 2008
**Cardiac Resynchronization Therapy (CRT) Inpatient Algorithm**

- **Patient on chronic optimal medical therapy prior to hospitalization**
  - LVEF ≤ 35%
  - NYHA Class III*  
  - Ambulatory NYHA Class IV*  
  - QRS ≥ 120 ms; NSR†

Refer for CRT/CRT-D†† evaluation during this hospitalization or schedule evaluation post-hospital discharge

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**Note:** Ongoing clinical trials are evaluating the benefit of CRT in NYHA Class II patients.

* Functional status as documented prior to current hospitalization while on chronic optimal medical therapy.
† CRT is a Class I guideline recommendation for patients with normal sinus rhythm (NSR). CRT is a Class IIa recommendation for patients with atrial fibrillation. Preliminary data suggest a possible functional improvement in these patients.
†† Inclusion of defibrillator to be based on ICD algorithm and physician discretion.
Reference Sources


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Sponsored by Medtronic, Inc.
April 2007
Revised September 2008
Anticoagulation Therapy in Atrial Fibrillation
Outpatient Algorithm

Patients with left ventricular systolic dysfunction and permanent, persistent, or paroxysmal AF*

Patients with prosthetic heart valves

Warfarin:
- Target INR 2.5
- INR range 2.0-3.0

Warfarin:
- Target INR 3.0
- INR range 2.5-3.5

Monitor INR at least monthly once therapeutic levels of anticoagulation have been established

*Atrial flutter should be similarly treated.

Contraindications to warfarin include:
- Allergy
- Pregnancy
- Risk of bleeding (such as active peptic ulcer disease); hemorrhagic stroke; other hemorrhage; hepatic failure; bleeding disorder; metastatic cancer; recent or planned surgery or biopsy procedure; other physician-documented bleeding risk
- High risk of fall documented by physician
- Psychosocial concerns (such as active psychosis; terminal illness/comfort care only; alcoholism or drug abuse)
- Other potential contraindication (such as seizure disorder; malignant hypertension; intracranial aneurysm, repaired or unrepaired)

Aspirin should be used in patients with absolute contraindications to oral anticoagulation.
Reference Sources


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Sponsored by Medtronic, Inc.
April 2007
Management of Volume Overload
Outpatient Algorithm

Carefully assess volume status

Signs or symptoms of volume overload

Yes

• Initiate or intensify dietary sodium restriction and fluid restriction as indicated
• Discontinue NSAIDs or COX-2 inhibitors

No

• If euvoletic, maintain sodium restriction, and if on a diuretic, maintain at current dose
• If signs or symptoms of hypovolemia, reduce dose or discontinue diuretic temporarily

Is the patient on a loop diuretic?

Yes

Initiate loop diuretic

No

Loop diuretic dosing adjustment for volume overload
Consider increasing dose or frequency of loop diuretic (e.g., 50-100% increase in furosemide dose per day [1-2 days or as needed]) per discretion of healthcare provider

Diuretic Maintenance Dosing – Refer to table on back of card

Monitoring and follow-up:
• Instruct patient on maintaining sodium-restrictive diet and, when indicated, limiting fluid intake
• Monitor daily weights
• Assess for signs and symptoms of hypovolemia/overdiuresis on every visit
• Assess for signs and symptoms of volume overload/congestion on every visit
• With recent adjustment of diuretic dose, electrolytes, BUN, and serum Cr should be monitored more frequently (e.g., at least weekly or more frequently if indicated)
• If worsening renal function occurs, the patient should be re-evaluated
### Diuretic Maintenance Dosing

<table>
<thead>
<tr>
<th>Scenario</th>
<th>Action</th>
</tr>
</thead>
<tbody>
<tr>
<td>Weight returned to baseline (identifiable cause for weight increase, e.g., nonadherence)</td>
<td>Resume original dose</td>
</tr>
<tr>
<td>Weight returned to baseline, but patient failed original dose previously, or no known cause for weight gain</td>
<td>Continue at current increased dose</td>
</tr>
<tr>
<td>Weight returned to baseline, but required two or more diuretic titrations</td>
<td>Resume dose prior to last increase (i.e., down one titration level)</td>
</tr>
<tr>
<td>Symptoms improved, but weight has not returned to baseline</td>
<td>Continue at current increased dose</td>
</tr>
<tr>
<td>Persistent symptoms with no change in weight</td>
<td>Continue next titration level</td>
</tr>
<tr>
<td>Persistent or worsening symptoms, and/or increase in weight, and/or history of frequent hospitalizations for volume overload</td>
<td>Consider adding metolazone, IV diuretic, or hospitalization. PO metolazone may be added in resistant cases for no more than 3 days, then reassess.4</td>
</tr>
</tbody>
</table>

1. Fluid restriction (< 2 L/day) is recommended in patients with moderate hyponatremia (serum sodium < 130 mEq/L) and should be considered to assist in treatment of fluid overload in other patients.
2. Consider also loosening the degree of dietary sodium restriction, then reassess.
3. Initial dose of loop diuretic at physician discretion. Careful observation for the development of side effects, including electrolyte abnormalities, symptomatic hypotension, and renal dysfunction, is recommended in patients treated with diuretics. Patients should undergo routine laboratory studies and clinical examination as dictated by their clinical response.
4. Addition of chlorothiazides or metolazone, once or twice daily, to loop diuretics should be considered in patients with persistent fluid retention despite high-dose loop diuretic therapy. But chronic daily use, especially of metolazone, should be avoided if possible because of the potential for electrolyte shifts and volume depletion. These drugs may be used periodically (every other day or weekly) to optimize fluid management. Volume status and electrolytes must be monitored closely when multiple diuretics are used. Consider administering metolazone 30-60 minutes before administration of loop diuretic.

**Reference Sources**

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Sponsored by Medtronic, Inc.
April 2007
Implantable Cardioverter Defibrillator (ICD) Therapy
Outpatient Algorithm

Secondary prevention
History of:
• Congenital high risk of VT/VF
• Cardiac arrest due to VT/VF
• Sustained VT/VF, spontaneous or induced by EPS
• Hemodynamically disabling VT
• Syncope

Primary prevention
Patient on chronic optimal medical therapy

LVEF
≤ 30%*

LVEF
31-40%

LVEF
≤ 35%*

Prior MI
≥ 40 days

NYHA
Class I

NYHA
Class I-III

NYHA
Class II-III

NSVT, CAD, prior MI, and inducible sustained VT/VF by EPS

Refer for ICD evaluation

Exclusion criteria/not indicated:
• NYHA Class IV (unless eligible for CRT)
• Cardiogenic shock or hypotension
• CABG or PTCA within past 3 months
• Candidate for coronary revascularization
• Irreversible brain damage from pre-existing cerebral disease
• Other disease with survival < 1 yr

MI
≤ 40 days

New-onset NIDCM†

Medically manage then reassess functional status and LVEF

* Class I recommendation.
† CMS coverage for primary prevention ICD implants: patients with nonischemic dilated cardiomyopathy (NIDCM) > 9 months, NYHA Class II and III heart failure, and measured LVEF ≤ 35%. Patients with NIDCM > 3 months and < 9 months, NYHA Class II or III heart failure, and measured LVEF ≤ 35% at this time are only covered by Medicare if these patients are enrolled in an FDA-approved category B IDE clinical trial, a trial under the CMS clinical trial policy, or the American College of Cardiology National Cardiovascular Data Registry (ACC-NCDR).
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Sponsored by Medtronic, Inc.
April 2007
Revised September 2008
Cardiac Resynchronization Therapy (CRT)
Outpatient Algorithm

Note: Ongoing clinical trials are evaluating the benefit of CRT in NYHA Class II patients.

* CRT is a Class I guideline recommendation for patients with normal sinus rhythm (NSR). CRT is a Class IIa recommendation for patients with atrial fibrillation. Preliminary data suggest a possible functional improvement in these patients.

† Inclusion of defibrillator to be based on ICD algorithm and physician discretion.
Reference Sources


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Sponsored by Medtronic, Inc.
April 2007
Revised September 2008
ICD Therapy is not indicated for patients who do not have a reasonable expectation of survival with an acceptable functional status for at least one year, even if they meet ICD implantation criteria specified in the algorithm. ICD therapy is not indicated for NYHA Class IV patients with drug-refractory congestive heart failure who are not candidates for cardiac transplantation or CRT-D.

† Functional status as documented prior to current hospitalization while on chronic optimal medical therapy.
References

1 CMS coverage for primary prevention ICD implants: patients with nonischemic dilated cardiomyopathy (NIDCM) > 9 months, NYHA Class II and III heart failure, and measured LVEF ≤ 35%. Patients with NIDCM > 3 months and < 9 months, NYHA Class II or III heart failure, and measured LVEF ≤ 35% at this time are only covered by Medicare if these patients are enrolled in an FDA-approved category B IDE clinical trial, a trial under the CMS clinical trial policy, or the American College of Cardiology National Cardiovascular Data Registry (ACC-NCDR).

Reference Source

Inpatient to Outpatient Transition Algorithm
for Medical and Device Therapy

**Secondary prevention:**
- Congenital high risk of VT/VF
- Cardiac arrest due to VT/VF
- Sustained VT/VF, spontaneous or induced by EPS
- Hemodynamically disabling VT
- Syncope

**Primary prevention**
Patient discharged from hospital with LVSD (with or without heart failure) or post-MI

**Post-discharge follow-up visit**

**Is patient currently receiving optimal medical therapy?**
- Yes
- No

**Has medical therapy been titrated to target dose?**
- Yes
- No

**Assess and document:**
- LVEF
- QRS duration
- NYHA Functional Class

**Secondary prevention:**
- Congenital high risk of VT/VF
- Cardiac arrest due to VT/VF
- Sustained VT/VF, spontaneous or induced by EPS
- Hemodynamically disabling VT
- Syncope

**Primary prevention**
Patient discharged from hospital with LVSD (with or without heart failure) or post-MI

**Initiate and uptitrated heart failure medications:**
- Beta blocker (evidence based)
- ACEI/ARB
- Aldosterone antagonist

**Uptitrated to target doses:**
- Beta blocker (evidence based)
- ACEI/ARB
- Aldosterone antagonist

**Yes**

**No**

**Assess and document:**
- LVEF
- QRS duration
- NYHA Functional Class

**MI ≤ 40 days**

**LVEF ≤ 30%**

**LVEF 31-40%**

**LVEF ≤ 35%**

**LVEF ≤ 35%**

**NYHA Class I**

**NYHA Class I**

**NYHA Class I-III**

**NYHA Class II-III**

**NYHA Class III or Ambulatory NYHA Class IV**

**Prior MI ≥ 40 days**

**New-onset NIDCM**

**Medically manage then reassess LVEF and functional status**

**NSVT, CAD, prior MI, and inducible sustained VT/VF by EPS**

**Refer for ICD evaluation unless contraindicated**

**QRS ≥ 120 ms, NSR**

**Refer for CRT/CRT-D evaluation unless contraindicated**
References

1 Patients with secondary indications for device therapy should undergo evaluation and device placement prior to hospital discharge.
2 Please see individual medication and device algorithms for details.
3 3-6 months of optimal medical therapy is suggested before reassessment of LVEF and functional status.
4 CMS coverage for primary prevention ICD implants: patients with nonischemic dilated cardiomyopathy (NIDCM) > 9 months, NYHA Class II and III heart failure, and measured LVEF ≤ 35%. Patients with NIDCM > 3 months and < 9 months, NYHA Class II or III heart failure, and measured LVEF ≤ 35% at this time are only covered by Medicare if these patients are enrolled in an FDA-approved category B IDE clinical trial, a trial under the CMS clinical trial policy, or the American College of Cardiology National Cardiovascular Data Registry (ACC-NCDR).

Reference Source

Guideline Recommendations for Heart Failure Device Therapy

Summary of recommendations for the use of ICD and/or CRT from the 2005 ACC/AHA Guideline Update for the Diagnosis and Management of Chronic Heart Failure in the Adult and the 2008 ACC/AHA/HRS Guidelines for Device-Based Therapy for Cardiac Rhythm Abnormalities.

<table>
<thead>
<tr>
<th>Classification of Recommendations</th>
<th>Conditions for which there is evidence and/or general agreement that a given procedure or treatment is beneficial, useful, and effective</th>
</tr>
</thead>
<tbody>
<tr>
<td>Class I</td>
<td>Conditions for which there is conflicting evidence and/or a divergence of opinion about the usefulness/efficacy of a procedure or treatment</td>
</tr>
<tr>
<td>Class IIa</td>
<td>Weight of evidence/opinion is in favor of usefulness/efficacy</td>
</tr>
<tr>
<td>Class IIb</td>
<td>Usefulness/efficacy is less well established by evidence/opinion</td>
</tr>
<tr>
<td>Class III</td>
<td>Conditions for which there is evidence and/or general agreement that a procedure/treatment is not useful/effective and in some cases may be harmful</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Level of Evidence</th>
</tr>
</thead>
<tbody>
<tr>
<td>Level of Evidence A</td>
</tr>
<tr>
<td>Level of Evidence B</td>
</tr>
<tr>
<td>Level of Evidence C</td>
</tr>
</tbody>
</table>

**Guideline Recommendations**

**Patients with Current or Prior Symptoms of HF (Stage C)**

**Patients with Reduced LVEF**

**Recommendations for ICD Therapy**

<table>
<thead>
<tr>
<th>Class I</th>
<th>An ICD is recommended as secondary prevention to prolong survival in patients with current or prior symptoms of HF and reduced LVEF who have a history of cardiac arrest, ventricular fibrillation, or hemodynamically destabilizing ventricular tachycardia</th>
</tr>
</thead>
<tbody>
<tr>
<td>Class I</td>
<td>ICD therapy is recommended for primary prevention to reduce total mortality by a reduction in sudden cardiac death in patients with ischemic heart disease who are at least 40 days post-MI, have an LVEF ≤ 30% with NYHA Class I symptoms or an LVEF 35% with NYHA Class II/III symptoms while undergoing chronic medical therapy and have a reasonable expectation of survival with a good functional status for more than 1 year</td>
</tr>
<tr>
<td>Class</td>
<td>Level of Evidence</td>
</tr>
<tr>
<td>-------</td>
<td>------------------</td>
</tr>
<tr>
<td>I</td>
<td>B</td>
</tr>
<tr>
<td>IIb</td>
<td>C</td>
</tr>
</tbody>
</table>

**Patients with Current or Prior Symptoms of HF (Stage C)**

**Patients with Reduced LVEF**

**Recommendations for CRT Therapy***

<table>
<thead>
<tr>
<th>Class</th>
<th>Level of Evidence</th>
<th>Recommendation</th>
</tr>
</thead>
<tbody>
<tr>
<td>I</td>
<td>A</td>
<td>Patients with an LVEF ≤ 35%, sinus rhythm, and NYHA Class III or ambulatory Class IV symptoms despite recommended, optimal medical therapy and who have cardiac dyssynchrony, which is currently defined as a QRS duration &gt; 120 ms, should receive cardiac resynchronization therapy unless contraindicated.</td>
</tr>
<tr>
<td>IIa</td>
<td>B</td>
<td>For patients with an LVEF ≤ 35%, a QRS duration of ≥ 120 ms, and AF, cardiac resynchronization therapy, with or without ICD therapy, is reasonable for the treatment of NYHA Class III or ambulatory Class IV symptoms on recommended optimal medical therapy.</td>
</tr>
<tr>
<td>IIa</td>
<td>C</td>
<td>For patients with an LVEF ≤ 35%, with NYHA Class III or ambulatory Class IV symptoms, who are receiving recommended optimal medical therapy and who have frequent dependence on ventricular pacing, cardiac resynchronization therapy is reasonable.</td>
</tr>
</tbody>
</table>

*Inclusion of an ICD to be based on ICD recommendations and physician discretion.

**Reference**


Developed by the SCA Prevention Medical Advisory Team based on the ACC/AHA 2005 Heart Failure Guidelines. This is a general algorithm to assist in the management of patients. This clinical tool is not intended to replace individual medical judgment or individual patient needs. Refer to the manufacturers’ prescribing information and/or instructions for use for the indications, contraindications, warnings, and precautions associated with the medications and devices referenced in these materials.

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