When should patients be considered for HeartMate™ LVAD therapy?

Patients with the following should be referred for evaluation for advanced heart failure therapies, including LVAD therapy.

1. **NYHA CLASS IIIIB OR IV HEART FAILURE (INTERMACS‡ 1-6):**

<table>
<thead>
<tr>
<th>NYHA CLASS</th>
<th>CLASS III</th>
<th>CLASS IIIB/IV</th>
<th>CLASS IV</th>
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<td>INR/7</td>
<td>5</td>
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<tr>
<td>INTERMACS registry advanced heart failure profiles</td>
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- Advanced NYHA III symptoms. Living comfortably with limited physical activity.
- Exertion limited. Walking wounded.
- Exertion intolerant. Housebound.
- Resting symptoms. Frequent flyer.
- Stable but inotropic dependent. Dependent stability.
- Progressive decline on inotropic support. Sliding on inotropes.
- Critical cardiogenic shock. Crash and burn.

2. **ANY ONE OF THE FOLLOWING HIGH-RISK CLINICAL TRIGGERS‡:**

- **I** IV Inotropes
- **N** NYHA IIIB/IV or persistently elevated natriuretic peptides
- **E** End-organ dysfunction (Cr > 1.8 mg/dL or BUN > 43 mg/dL)
- **E** Ejection fraction ≤ 35%
- **D** Defibrillator shocks
- **H** Hospitalizations > 1
- **E** Edema (or elevated PA pressure) despite escalating diuretics
- **L** Low blood pressure, high heart rate
- **P** Prognostic medication — progressive intolerance or down-titration GDMT

**Additional patient referral considerations:**

- CRT nonresponder
- Physical activity limited or impaired quality of life

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HeartMate.com
St. Jude Medical is now Abbott.
Rx Only
Important Safety Information
Brief Summary: Prior to using these devices, please review the Instructions for Use for a complete listing of indications, contraindications, warnings, precautions, potential adverse events and directions for use.

HeartMate 3™ LVAS Indications: The HeartMate 3 Left Ventricular Assist System is indicated for providing short-term hemodynamic support (e.g., bridge to transplant or bridge to myocardial recovery) in patients with advanced refractory left ventricular heart failure.

HeartMate II™ LVAS Indications: The HeartMate II Left Ventricular Assist System is indicated for use as a “bridge to transplantation” for cardiac transplant candidates who are at risk of imminent death from non-reversible left ventricular failure. It is also indicated for use in patients with New York Heart Association (NYHA) Class III or IV end-stage ventricular failure, who have received optimal medical therapy for at least 45 of the last 60 days, and who are not candidates for cardiac transplantation. The HeartMate II Left Ventricular Assist System is intended for use both inside and outside of the hospital, or for transportation of Left Ventricular Assist Device patients via ground ambulance, airplane, or helicopter.

HeartMate 3 LVAS and HeartMate II LVAS Contraindications: The HeartMate 3 and HeartMate II Left Ventricular Assist Systems are contraindicated for patients who cannot tolerate, or who are allergic to, anticoagulation therapy.

HeartMate 3 LVAS and HeartMate II LVAS Adverse Events: Adverse events that may be associated with the use of the HeartMate 3 or HeartMate II Left Ventricular Assist System are listed below:
- death, bleeding, cardiac arrhythmia, localized infection, right heart failure, respiratory failure, device malfunctions, driveline infection, renal dysfunction, sepsis, stroke, other neurological event (not stroke-related), hepatic dysfunction, psychiatric episode, venous thromboembolism, hypertension, arterial non-central nervous system (CNS), thromboembolism, pericardial fluid collection, pump pocket or pseudo pump pocket infection, myocardial infarction, wound dehiscence, hemolysis (not associated with suspected device thrombosis) and possible pump thrombosis.

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