When to Refer for Advanced Heart Failure Evaluation

RECOGNIZE THE SYMPTOMS OF ADVANCED HEART FAILURE[1]

NYHA CLASS	CLASS III	CLASS IIIB	CLASS IV (AMBULATORY)		CLASS IV (ON INOTROPES)		
	Markedly symptomatic during daily activities, asymptomatic only at rest		Severe limitations, symptoms even at rest				
INTERMACS‡ PROFILES	7	6	5	4	3	2	1
	Advanced NYHA III symptoms	Exertion limited	Exertion intolerant	Resting symptoms	Stable but inotrope dependent	Progressive decline on inotropic support	Critical cardiogenic shock

IDENTIFY ANY OF THE FOLLOWING TRIGGERS FOR REFERRAL TO A HEART FAILURE SPECIALIST[2]

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	EF ≤ 35%
D	Defibrillator shocks
H	Hospitalizations > 1 with heart failure
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 CONSIDERATIONS FOR REFERRAL

- CRT non-responder
- Physical activity limited or impaired QOL

Abbott

Clinical Considerations*

PA PRESSURE REMOTE MONITORING

CardioMEMS™ HF System

PATIENT PROFILE:

- NYHA Class III and ≥ 1 heart failure hospitalization in past 12 months
- Fluid volumes are hard to know or manage
- HFpEF or HFrEF (no EF requirement)

ADDITIONAL CONSIDERATIONS:

- Monitor hemodynamic pressures for additional predictive indicators beyond patient symptoms alone
- Support patients with remote hemodynamic monitoring if they live far away or have difficulty visiting the clinic

CONSIDERATIONS FOR ADVANCED HEART FAILURE THERAPY EVALUATION:

- Heart failure progression to Class IIIB or IV
- Recurring Merlin.net™ Patient Care Network notifications for elevated pressures outside thresholds despite maximized medical management (GDMT, diuretics, vasodilators)
- Heart failure rehospitalization(s)

LEFT VENTRICULAR ASSIST DEVICE (LVAD) THERAPY

HeartMate 3™ LVAD

PATIENT PROFILE:

- NYHA Class IIIB or IV
- Heart failure hospitalization(s)
- Unresponsive to diuretics or neurohormonal agents

ADDITIONAL CONSIDERATIONS:

- EF < 35%
- Persistently high PA pressures
- Elevated pro-BNP or BNP
- 6MWD < 300 m
- Echo exam unchanged

6MWD = six-minute walk distance
BNP = brain natriuretic peptide
BUN = blood urea nitrogen
CRT = cardiac resynchronization therapy
EF = ejection fraction
HFpEF = heart failure with preserved ejection fraction
HFrEF = heart failure with reduced ejection fraction
IV = intravenous
LVAD = left ventricular assist device
NYHA = New York Heart Association
PA = pulmonary artery

*Clinicians are responsible for making independent, patient-specific, clinical determinations regarding the medical necessity of any advanced interventions and for ensuring that all medical decisions are in the clinical best interest of the patient. Safety and effectiveness of the combined use of the CardioMEMS™ HF System with HeartMate 3™ LVAD therapy have not been determined.

1. Rogers JG, Boyle AJ, O'Connell JB, et al. Risk Assessment and Comparative Effectiveness of Left Ventricular Assist Device and Medical Management in Ambulatory Heart Failure Patients: Design and Rationale of the ROADMAP Clinical Trial. *Am Heart J*. 2015 Feb;169(2):205-210.e20.
2. Yancy CW, Januzzi JL Jr, Allen LA, et al. 2017 ACC Expert Consensus Decision Pathway for Optimization of Heart Failure Treatment: Answers to 10 Pivotal Issues About Heart Failure With Reduced Ejection Fraction: A Report of the American College of Cardiology Task Force on Expert Consensus Decision Pathways [published correction appears in *J Am Coll Cardiol*. November 13, 2018;72(20):2549]. *J Am Coll Cardiol*. 2018;71(2):201-230.

Abbott
One St. Jude Medical Dr., St. Paul, MN 55117 USA, Tel: 1 651 756 2000
Cardiovascular.Abbott

Rx Only
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.

CardioMEMS™ HF System Indications and Usage: The CardioMEMS™ HF System is indicated for wirelessly measuring and monitoring pulmonary artery (PA) pressure and heart rate in New York Heart Association (NYHA) Class III heart failure patients who have been hospitalized for heart failure in the previous year. The hemodynamic data are used by physicians for heart failure management and with the goal of reducing heart failure hospitalizations.

CardioMEMS™ HF System Contraindications: The CardioMEMS HF System is contraindicated for patients with an inability to take dual antiplatelet or anticoagulants for one month post implant.

CardioMEMS™ HF System Potential Adverse Events: Potential adverse events associated with the implantation procedure include, but are not limited to, the following: infection, arrhythmias, bleeding, hematoma, thrombus, myocardial infarction, transient ischemic attack, stroke, death, and device embolization.

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

HeartMate 3™ LVAS Contraindications: The HeartMate 3 Left Ventricular Assist System is contraindicated for patients who cannot tolerate, or who are allergic to, anticoagulation therapy.

HeartMate 3™ LVAS Adverse Events: Adverse events that may be associated with the use of the HeartMate 3 Left Ventricular Assist System are: 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 pocket infection, myocardial infarction, wound dehiscence, hemolysis (not associated with suspected device thrombosis) or pump thrombosis.

MAT-2008794 v1.0 | Item approved for U.S. use only.

Abbott