

November 9, 2012

HEART FAILURE TREATMENT UTILIZING A VENTRICULAR ASSIST DEVICE OR TOTAL ARTIFICIAL HEART: PATIENT SELECTION AND FUNDING

1. PURPOSE: This Veterans Health Administration (VHA) Directive provides the policy for the use and funding of Ventricular Assist Device (VAD) therapy for destination and bridge to transplantation and Total Artificial Heart (TAH) therapy for bridge to transplantation, including guidelines for patient selection. **AUTHORITY: Title 38 United States Code (U.S.C.) 7301(b).**

NOTE: *This policy does not apply to temporary VAD placement for failure to wean from cardiopulmonary bypass during a scheduled or emergency cardiac surgery procedure (termed postcardiotomy) or to the placement of a percutaneous left VAD in the cardiac catheterization laboratory.*

2. BACKGROUND

a. Heart transplantation is an established treatment modality to cure the symptoms of heart failure and to prolong life. Unfortunately, far more people are waiting for heart transplantation than can be accommodated by the current donor availability. Moreover, not all patients with failing hearts are eligible for transplantation based on age and co-morbidity. The result is a significant number of Veterans with heart failure refractory to medical therapy that would benefit from VAD or TAH therapy.

b. The VAD is a mechanical pump surgically implanted to support the heart's ventricular (pump) function without replacing the failing heart. Implantation has been shown to improve the survival, quality of life, and functional capacity in patients with heart failure who are unresponsive to medical therapy. Following implantation and recovery, patients are often discharged from the hospital, regardless of whether the VAD is placed as destination therapy or as a bridge to transplantation.

(1) Candidates for VAD implantation for destination therapy must meet the following conditions:

(a) Classified by the New York Heart Association (NYHA) as Class IV, advanced-stage heart failure;

(b) Documented age or co-morbid condition that precludes the patient from being a heart transplant candidate;

(c) Refractory to optimal medical management for at least 45 of the last 60 days prior to the VAD implantation, or intra-aortic balloon pump (IABP) dependent for 7 days, or intravenous inotrope dependent for 14 days;

(d) Documented left ventricular ejection fraction (LVEF) of less than (<) 25 percent;

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(e) Demonstrated functional limitation with a peak oxygen consumption of < 14 milliliters (ml)/ kilogram (kg)/minute (min) unless IABP or inotrope dependent, or physically unable to perform this diagnostic test.

(2) VAD implantation for destination therapy can be performed by the following VHA facilities:

(a) An approved VHA in-house heart transplantation program.

(b) An in-house VHA cardiac surgery program that has been approved for VAD destination therapy according to current VHA policy regarding the restructuring of clinical programs.

NOTE: The Veteran who receives a VAD for destination therapy that later improves remains eligible for consideration for heart transplantation by a VHA heart transplantation program.

(3) Candidates for VAD for bridge to transplantation must meet the following conditions:

(a) Approved and listed by a VHA heart transplant program as a candidate for heart transplantation with the United Network for Organ Sharing (UNOS);

(b) Classified by the NYHA as Class IV, advanced-stage heart failure;

(c) Refractory to optimal medical management for at least 45 of the last 60 days prior to the VAD implantation, IABP dependent for 7 days, or intravenous inotrope dependent for 14 days;

(d) Documented LVEF of < 25 percent; and

(e) Demonstrated functional limitation with a peak oxygen consumption of < 14 ml/kg/min, unless IABP or inotrope dependent, or physically unable to perform this diagnostic test.

c. The TAH is a biventricular mechanical pump that is surgically implanted to replace the failing heart and is recognized as an effective bridge to transplantation therapy.

(1) Alternatively, two VADs (bi-VAD) can be implanted to support the right side and left side of the heart for similar purpose. Typically, patients receiving TAH or bi-VAD implants remain hospitalized until heart transplantation is performed. Furthermore, removal or failure of the TAH device results in death.

(2) Candidates for TAH or bi-VAD implantation for bridge to transplantation must meet the following conditions:

(a) Approved and listed by a VHA heart transplant program as a candidate for heart transplantation with the UNOS;

(b) Classified by NYHA as Class IV, advanced-stage heart failure;

(c) Dependent upon IABP or intravenous inotrope therapy; and

(d) Untreatable with a single VAD alone.

3. POLICY: It is VHA policy that a VAD or TAH therapy is provided at approved VHA Surgical Programs following the procedures outlined in this Directive.

4. ACTION

a. **VHA Chief Financial Officer.** VHA Chief Financial Officer is responsible for:

(1) Providing special purpose funding to the National Surgery Office (NSO) at the approved funding level for that fiscal year. These funds must be used to support the VAD or TAH surgical procedure excluding the cost of the device itself. Costs for the VAD and TAH devices are funded from the VHA prosthetics special purpose funds when the procedure is performed at an approved VHA in-house cardiac surgery program or an approved VHA heart transplant program.

(2) Ensuring special purpose funds are not used for the cost of the VAD or TAH device, or the care and treatment of the Veteran receiving either a VAD or TAH when the implantation is performed outside VA. The facility Director, VISN (Veterans Integrated Systems Network) Director, or designee, may elect to provide care and treatment to the Veteran at a non-VA facility through non-VA care. However, once the Veteran has been determined to be eligible and accepted for care and treatment at a VA facility, VA assumes the costs of maintenance of the VAD, including disposable accessory equipment or replacement of the device if clinically indicated.

b. **VHA National Surgery Office (NSO).** The VHA NSO is responsible for providing oversight to the in-house VHA cardiac surgery programs and the VHA heart transplantation programs.

c. **VHA National Director of Surgery.** The National Director of Surgery is responsible for:

(1) Establishing a database for tracking Veterans who underwent VAD or TAH implantation by a VA medical facility approved for VAD or TAH implantation;

(2) Monitoring patient outcomes;

(3) Maintaining a list of VHA Surgical Programs approved for VAD and TAH implantation; and

(4) Administering and providing timely distribution of VHA Central Office special purpose funds to an approved in-house VHA cardiac surgery program or an approved VHA heart transplantation program for the care and treatment of the Veteran receiving a VAD or TAH.

d. **Veterans Integrated Service Network (VISN) Director.** Each VISN Director must ensure that necessary and appropriate health care is provided to all enrolled or otherwise eligible Veterans.

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e. **Medical Facility Director and Chief of Staff.** The Medical facility Director and Chief of Staff are responsible for ensuring:

(1) Patients are provided all of the care included in the Department of Veterans Affairs (VA) medical benefits package.

(2) Veterans meets all of the criteria for VAD or TAH implantation as outlined in subparagraphs 2b(1), 2b(3), and 2c(2).

(3) Timely submission of patient information is completed as requested by the NSO prior to or following VAD or TAH implantation.

(4) A plan for future urgent care of the patient with a VAD for destination therapy upon discharge is in place between the referring VA medical facility and the VA medical facility implanting the device and must be documented in the medical record prior to VAD implantation.

(5) Each Veteran with an implanted VAD is informed of the following:

(a) After the Veteran is discharged home and in the event the Veteran requires immediate medical attention, the Veteran or caregiver must call 911 and activate the community emergency medical treatment system.

(b) If stable for transport, the Veteran should present to the referring VA medical facility for evaluation and the implanting VA medical facility must be contacted (given a 24 hour a day, 7 days a week (24/7) contact number) for further management instruction.

(c) Further care and treatment of the Veteran may require transfer to either the VA medical facility that implanted the device, an established VA medical facility approved for VAD implantation, or a non-VA medical facility with appropriate expertise based upon the clinical circumstances of the Veteran.

f. **Chief of Surgery at a Medical Facility Approved for VAD or TAH implantation.** The Chief of Surgery at a Medical Facility with an approved VAD or TAH program is responsible for ensuring:

(1) The facility has the appropriate infrastructure complexity, including qualified cardiac surgery providers, cardiology support staff and intensive care expertise and resources to provide care and treatment of the Veteran with a failing heart before and after VAD or TAH implantation.

(2) The Medical Facility Director and Chief of Staff receive immediate notification if and when the facility fails to maintain appropriate infrastructure complexity to support the Veteran with a failing heart before and after VAD or TAH implantation.

(3) Veterans with an implanted VAD, discharged to the Veteran's home or discharged to a referring VA medical facility, have an established discharge plan, including instructions for device management, and 24/7 contact numbers.

(4) The medical record contains clear documentation of any handoff of care to a referring VA medical facility, including the name of the accepting and responsible referring medical facility provider if and when the Veteran with a VAD is discharged from the approved VAD or TAH program.

5. REFERENCES

a. Slaughter, M.S., Rogers, J.G., Milano, C.A., et al. Advanced Heart Failure Treated with Continuous-Flow Left Ventricular Assist Device. New England Journal of Medicine 2009, 361: 2241-2251.

b. National Coverage Determination (NCD) for Artificial Hearts and Related Devices (20.9), the Centers for Medicare and Medicaid Services.

c. Hurst, J.W., Morris, D.C., Alexander, R.W. The Use of the New York Heart Association's Classification of Cardiovascular Disease as Part of the Patient's Complete Problem List. Clinical Cardiology, 1999; 22:385-390

6. FOLLOW-UP RESPONSIBILITY: The VHA NSO (10NC2) is responsible for the contents of this Directive. Questions may be referred to the National Director of Surgery at 202-461-7148.

7. RESCISSIONS: VHA Directive 2001-004, Funding of Left Ventricular Assist Device, is rescinded. This VHA Directive expires November 30, 2017.

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